

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

CARLOS PÉREZ-COTAPOS UGARTE,
MARIA ISABEL URETA BAZÁN,
CARLOS PÉREZ-COTAPOS
SUBERCASEAUX, INVERSIONES ANE
MIREN LIMITADA, SHERYL GROVE, and
HOORIEH ALAGHEMAND, Individually
and on Behalf of All Others Similarly
Situated,

Plaintiff,

v.

CASSAVA SCIENCES, INC., REMI
BARBIER, RICHARD JON BARRY,
LINDSAY BURNS, JAMES W. KUPIEC,
and ERIC SCHOEN,

Defendants.

Case No. 1:24-CV-1525-DAE

**AMENDED COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

CLASS ACTION

Demand for Jury Trial

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Lead Plaintiffs Carlos Pérez-Cotapos Ugarte, Maria Isabel Ureta Bazán, Carlos Pérez-Cotapos Subercaseaux, and Inversiones Ane Miren Limitada (collectively, the “Pérez-Cotapos Family” or “Lead Plaintiffs”) and additional Plaintiffs Sheryl Grove and Hoorieh Alaghemand (together with Lead Plaintiffs, “Plaintiffs”), individually and on behalf of all other persons similarly situated, allege the following based upon their personal knowledge as to the allegations concerning them and upon information and belief as to all other matters. Plaintiffs’ information and belief is based upon the investigation conducted by Co-Lead Counsel, which included, *inter alia*: (a) review and analysis of relevant regulatory filings made by Cassava Sciences, Inc. (“Cassava” or the “Company”) with the United States Securities and Exchange Commission (the “SEC”); (b) review and analysis of Cassava’s public documents, call transcripts, press releases, and media reports issued by or disseminated by Cassava; (c) review and analysis of securities analysts’ reports concerning the Company; and (d) review of other publicly available information concerning Cassava and its current and former employees, officers, directors, and third-party collaborators.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Cassava securities between October 13, 2023 through March 25, 2025, inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder (the “Class”).

2. Cassava is a clinical-stage biotechnology company based in Austin, Texas. During the Class Period, Cassava had only one therapeutic drug candidate, simufilam (formerly known as PTI-125), which was in clinical trials for the proposed treatment of Alzheimer’s disease.

3. Before the Class Period, Cassava—at times, operating under its previous name, Pain Therapeutics, Inc. (“Pain Therapeutics”)—completed a Phase 1 clinical study for simufilam and two Phase 2 clinical programs: a Phase 2a study (the “Phase 2a Study”) and a Phase 2b study (the “Phase 2b Study”). The Company also began a third Phase 2 trial (the “Phase 2 Study”), which was not complete until the Class Period, involving a larger patient population and duration than the earlier Phase 2 clinical trials.

4. Beginning in August 2021, the Phase 2b Study became embroiled in controversy when Dr. Hoau-Yan Wang of the City University of New York (“CUNY”), the longtime Cassava consultant who performed the final analysis of the cerebrospinal fluid (“CSF”) samples for the Phase 2b Study, was accused of research misconduct and data manipulation.

5. Specifically, a citizen petition raised concerns about data and analyses in foundational research papers authored by Dr. Wang and Defendant Lindsay Burns and used to obtain grants to study simufilam, identifying anomalies indicative of data manipulation. The citizen petition also called into question the Phase 2b Study results insofar as the CSF samples were first analyzed by an outside lab, which found simufilam to be ineffective, before Dr. Wang, a financially interested Cassava consultant, conducted a re-analysis that purportedly showed improvements in assessments of cognitive faculties.

6. That controversy kicked off years of Defendants making false and misleading statements that downplayed the accusations of research misconduct related to the Phase 2b Study. Even when confronted with substantial government investigations into the same, the Company emphatically denied the accusations of wrongdoing, falsely assuring investors that they were unfounded and driven by financially interested short sellers. They also continued to tout the Phase

2b Study results until after Dr. Wang was indicted for falsifying data to obtain grants from the National Institute of Health (“NIH”) for Cassava.

7. The Class Period begins the day after a report about CUNY’s internal investigation of Dr. Wang was leaked. The report described an internal investigation of thirty-one allegations of research misconduct by Dr. Wang and “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang for 14 of the 31 allegations,” including, *inter alia*, “image aberrations that may be consistent with the fabrication/manipulation of the data.” Significantly, CUNY’s report also implicated then-Senior Vice President of Neuroscience at Cassava, Defendant Burns, stating that she also bore responsibility for some of the alleged misconduct.

8. After the market closed on October 12, 2023, the Company issued a false and misleading response that denied the findings in the CUNY report, emphasizing that Cassava played no role in CUNY’s investigation, CUNY had “turned down all requests for information and offers of assistance from Cassava,” and CUNY had not interviewed any Cassava employees, and thus, CUNY had “no legitimate basis to make accusations against the Company or its employees.” The Company also questioned the authenticity of the leaked report.

9. Defendants continued to mislead investors about the research misconduct during the Phase 2b Study and the related investigations. The Company’s Q3 2023 quarterly report filed with the SEC on November 7, 2023, and Q1 2024 quarterly report filed with the SEC on May 10, 2024, downplayed the government investigations that had been ongoing since 2021, stating “[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors,” which misleadingly suggested that there was no evidence of *any* research misconduct when that was not the case.

10. Defendants took it a step further, pointing to an internal investigation by an outside firm to support that there was no evidence of *any* research misconduct. The Company’s Board of Directors (the “Board”) retained the law firm Orrick Herrington & Sutcliffe LLP (“Orrick”) to investigate the allegations of research misconduct against “certain of [the Company’s] employees and third-party collaborators,” including Dr. Wang, during the Phase 2b clinical trial, and the Company’s 2023 annual report, filed on February 28, 2024, disclosed that Orrick had “found no evidence to substantiate the allegations that *the Company or its employees* engaged in or were aware of research misconduct” (emphasis added).

11. Meanwhile, Defendants continued to tout the Phase 2b Study results, including the “[e]ncouraging effects on cognition” observed during the Phase 2b Study, as well as “improvements in CSF biomarkers of disease pathology, neurodegeneration, and neuroinflammation,” and “improvements in validated tests of episodic memory and spatial working memory” versus patients on placebo.

12. However, unbeknownst to investors, when Defendants made these misstatements, they knew, or, absent severe recklessness, should have known, information that rendered these statements false or misleading. Specifically, *over a year before the earliest misstatement, the Company had conducted an audit of Dr. Wang’s laboratory at CUNY* related to his work on the Phase 2b Study *and found that it “was unacceptable and temporarily not qualified to provide biomarker analysis and research for services for any future Cassava studies”* (emphasis added). Thus, Defendants knew, or should have known, that the allegations of research misconduct related to the Phase 2b Study were legitimate.

13. Further, any reasonable investigation into whether Burns bore any responsibility for the alleged research misconduct before the Company categorically denied the legitimacy of the

CUNY report would have revealed the evidence that the Company had in its possession—an email from Burns to Dr. Wang that enabled him to unblind himself as to some participants in the Phase 2b Study before he conducted the final analysis—which supported that Burns bore some responsibility.

14. Defendants’ motivation for misleading investors about the controversy was clear: Cassava’s financial success and future vitality was entirely dependent on the successful development of simufilam for commercial sale, as Cassava did not generate *any* revenue and consistently lost money quarter over quarter. Thus, Defendants were highly motivated to ensure that investors believed that simufilam was still on track for approval, including so that they could raise additional capital, through warrant distributions, to support the continued development of simufilam.

15. However, Defendants’ efforts to sweep this controversy under the rug were unsuccessful, and the truth about the research misconduct during the Phase 2b Study began to trickle out on June 28, 2024, when Dr. Wang was indicted.

16. Upon this news, Cassava’s stock fell from a closing price of \$18.95 per share on June 27, 2024 to close at \$12.35 per share on June 28, 2024, a decline of about 34.83%.

17. The truth continued to emerge on July 1, 2024, when the Company announced that the DOJ and SEC had been investigating Cassava and two senior employees related to the Phase 2b clinical trial, and the Company identified the email that Burns sent to Dr. Wang that enabled him to unblind himself as to some study participants before conducting the final analysis for the Phase 2b Study.

18. Upon this news, the Company’s stock declined even further, falling from a closing price of \$12.35 per share on June 28, 2024 to close at \$12.14 per share on July 1, 2024.

19. Defendants, nevertheless, continued to mislead investors about who was involved in the alleged research misconduct. On July 17, 2024, the Company issued a press release revealing that then-President and CEO, Defendant Remi Barbier, had resigned and that his wife, Burns, and the Company had agreed that she would step down from her employment. While touting the Company's commitment to transparency, the Company failed to disclose that the reason for Barbier and Burns' departure was their involvement in the alleged research misconduct.

20. Shortly thereafter, on August 8, 2024, the extent of the government investigations into the alleged research misconduct and the unreliability of the Phase 2b Study was revealed for the first time. The Company disclosed that it was close to an agreement with the SEC to resolve potential claims for \$40 million, and that investors "should not place undue reliance" on the Phase 2b Study results.

21. Upon this news, Cassava's stock fell from a closing price of \$30.20 per share on August 7, 2024 to close at \$26.02 per share on August 8, 2024, a decline of about 13.84%.

22. The full truth about who was involved in the alleged misconduct emerged on September 26, 2024 after the close of trading, when the SEC filed charges against Cassava, Barbier, and Burns related to their misleading statements about the results of Phase 2b Study and announced that they had agreed to a settlement.

23. Upon this news, Cassava's stock declined roughly 10.61%, from a closing price of \$31.87 on September 26, 2024 to close at \$28.49 on September 27, 2024.

24. Defendants' deception did not end there. In addition to misleading the market about the research misconduct during the Phase 2b Study and the investigations related thereto, Defendants also made, or caused to be issued, a series of misstatements related to the Phase 2 Study results.

25. Before the truth about the research misconduct during the Phase 2b Study and the related investigations emerged, the Company had completed the Phase 2 Study and reported the topline results on February 7, 2024. Thus, while Defendants were attempting to distance the Company from the controversy surrounding the Phase 2b Study in order to make simufilam's prospects appear favorable, they also began emphasizing the Phase 2 Study results as supportive of simufilam's potential. For example, Defendant James W. Kupiec later described: "the data from the [Phase 2 Study] was *remarkable* in that patients with mild dementia apparently had no significant decline during that two-year treatment period" (emphasis added).

26. Analysts bought it. Jones Research issued a report on February 7, 2024, titled "2-Year Data Continue to Show *Robust Benefits*, Primarily in Mild Alzheimer's Patients" (emphasis added) and recommended a "Buy" rating for Cassava. Later that month, on February 28, 2024, Jones Research issued another report that indicated the Phase 2 Study results were supportive of the ongoing Phase 3 clinical trials. Specifically, the report stated: "*In support of the Phase 3 program*, Cassava recently announced that mild Alzheimer's disease patients who received simufilam continuously for 24 months showed no decline in cognition scores . . . in a two-year open-label safety study" (emphasis added).

27. When the truth about the research misconduct and the unreliability of the Phase 2b Study results finally came to light, Defendants doubled down on the Phase 2 Study results, stating: "*the Company believes that it is more helpful to focus on examining the two-year Phase 2 safety study that concluded earlier this year*" (emphasis added).

28. But the Phase 2 Study results were not what they seemed. While Defendants repeatedly touted the Phase 2 Study results showing "No Decline in Cognition Scores in Patients

with Mild Alzheimer’s Disease Who Received Simufilam Continuously For 24 Months,” Defendants misrepresented two critical components of the Phase 2 Study results.

29. First, the Phase 2 Study results were based on an analysis of only roughly *half* of the intent-to-treat (“ITT”) population, *i.e.*, all randomized patients, regardless of treatment. The ITT population for the Phase 2 Study was 219 patients, a significant increase from their prior Phase 2 clinical studies: only 13 participants for the Phase 2a Study and 64 participants for the Phase 2b Study. Although Defendants reported that Phase 2 results were based on the Full Analysis Set (“FAS”), the announced results were, in fact, based only on patients that who completed cognition testing at baseline *and month 24*, the end of the trial. Thus, patients who were not available for a cognition assessment at the conclusion of the trial or who dropped out of the trial before completion were excluded from the patient population analyzed. This approach is in violation of ICH E9 Statistical Principles for Clinical trials, a document that provides guidance on the analysis of clinical trials and is adopted as official policy by the FDA. ICH E9 does not allow patients who discontinued during the course of the trial to be excluded from the FAS.

30. Second, despite Defendants’ rosy portrayals of the results, patients with mild Alzheimer’s disease actually performed similarly whether they were on simufilam or placebo, with no consistent trends. Thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer’s disease population was inconclusive and the Phase 2 Study results were not as “remarkable” as Defendants led investors to believe.

31. Third, in addition to using a non-compliant FAS approach without disclosing the details of their methodology, Defendants failed to disclose that there would be a substantial change to the more rigorous ITT analysis in Phase 3. As such, investors lacked the information to

understand that end-of-trial Phase 2 results were likely to be a poor predictor of Phase 3 performance.

32. The previously undisclosed risk that Defendants were touting the Phase 2 Study results as supportive of simufilam's progress, but the results were not as "remarkable" as Defendants led investors to believe, materialized when the Company revealed on November 25, 2024, that the first of the Phase 3 trials, RETHINK-ALZ, failed and that the Company would be discontinuing the second Phase 3 trial, REFOCUS-ALZ.

33. Upon this news, Cassava's stock fell from a closing price of \$26.48 per share on November 22, 2024 to close at \$4.30 per share on November 25, 2024, a decline of about 83.76%.

34. An analyst from H.C. Wainwright downgraded Cassava's rating to "Neutral" on November 26, 2024, expressing surprise that the trial failed given the promising Phase 2 study results: "We are surprised by the results *as Phase 2 studies suggested mechanism of action (MOA)-based and biomarker-based results supported high potential for a positive result with simufilam treatment vs. placebo*" (emphasis added).

35. The risk continued to materialize on March 25, 2025, when the Company announced that simufilam likewise did not meet any endpoints for the second Phase 3 trial, REFOCUS-ALZ, and that the Company would be discontinuing its Alzheimer's disease development program with simufilam. Upon this news, Cassava's stock fell from a closing price of \$2.80 per share on March 24, 2025 to close at \$1.90 per share on March 25, 2025, a 32.14% drop.

JURISDICTION AND VENUE

36. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R.

§240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

37. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b), as Cassava maintains its headquarters in this Judicial District, conducts substantial business in this Judicial District, and a substantial part of the acts or conduct in furtherance of the alleged fraud, including the preparation and dissemination of materially false and misleading information to the public, occurred in this Judicial District.

38. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities exchange.

PARTIES

39. Lead Plaintiffs Carlos Pérez-Cotapos Ugarte, Maria Isabel Ureta Bazán, Carlos Pérez-Cotapos Subercaseaux, and Inversiones Ane Miren Limitada, as set forth in the Certifications previously submitted to the Court (ECF No. 25-4), acquired Cassava securities at artificially inflated prices during the Class Period and were damaged upon the revelation of the alleged corrective disclosures and when the previously undisclosed risk materialized.

40. Additional Plaintiff Sheryl Grove, as set forth in the Certification attached hereto as Exhibit A, acquired Cassava securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures and when the previously undisclosed risk materialized.

41. Additional Plaintiff Hoorieh Alaghemand, as set forth in the Certification previously submitted to the Court (ECF No. 14-2), acquired Cassava securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures and when the previously undisclosed risk materialized.

42. Cassava Sciences, Inc. is a Delaware corporation with its principal executive offices located at 6801 N. Capital of Texas Highway, Building 1, Suite 300, Austin, TX 78731. During the Class Period, the Company's securities traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "SAVA." Cassava previously operated under the name Pain Therapeutics, Inc. until its name was changed in March 2019.

43. Defendant Remi Barbier ("Barbier") served as Cassava's President and Chief Executive Officer during the Class Period until he resigned on July 15, 2024. He remained employed by the Company until September 13, 2024 in a non-executive capacity, without duties or responsibilities.

44. Defendant Richard (Rick) J. Barry ("Barry") has served as a Director of the Company since 2021. He was appointed Executive Chairman of the Board and the Company's principal executive officer on July 17, 2024 while the Company undertook a search for a new permanent CEO. Barry was named the permanent CEO of the Company on September 9, 2024, and another individual assumed the role of Chairman of the Board.

45. Defendant Lindsay Burns, PhD ("Burns"), served as Cassava's Senior Vice President of Neuroscience during the Class Period and reported to Defendant James W. Kupiec until July 16, 2024, when Burns and the Company agreed that she would "step down from her employment with the Company, effective immediately." At all relevant times, Barbier and Burns were married.

46. Defendant James (Jim) W. Kupiec, M.D. ("Kupiec") was the Chief Medical Officer of Cassava during the Class Period. Prior to the Class Period, between January 4, 2021 and December 20, 2022, Kupiec was the Chief Clinical Development Officer of Cassava and served as a member of the executive management team.

47. Defendant Eric Schoen (“Schoen”) was, at all relevant times, the Chief Financial Officer of Cassava.

48. Defendants Barbier, Barry, Burns, Kupiec, and Schoen are sometimes referred to herein as the “Individual Defendants.” Cassava together with the Individual Defendants are referred to herein as the “Defendants.” The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Cassava’s reports to the SEC, press releases, presentations, and other market communications. The Individual Defendants were provided with copies of the Company’s SEC filings, press releases, and other market communications alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false or misleading.

SUBSTANTIVE ALLEGATIONS

Barbier and the Company’s History of Deception

49. Cassava is a clinical stage biotechnology company that, until 2019, operated under the name Pain Therapeutics. Barbier founded Pain Therapeutics and ran it as President, CEO, and Chairman of the Board since its inception. Pain Therapeutic’s leading drug candidate was REMOXY, an abuse-deterrent form of oxycodone to treat severe chronic pain. The Company also began developing simufilam while it still operated as Pain Therapeutics.

50. Under Barbier’s management, Pain Therapeutics likewise faced legal scrutiny. Pain Therapeutics, Barbier, and other Pain Therapeutics executives were sued for securities fraud for misleading investors about REMOXY, which had been submitted to the FDA for approval, by

concealing material facts about the drug that would have alerted investors to its substantial risk of rejection by the FDA.

51. That case ultimately settled on the eve of trial, after the Court denied the defendants' motion for summary judgment, finding, *inter alia*, that there was sufficient evidence that Barbier knowingly misled investors about issues with REMOXY for the case to proceed to trial.

Cassava Develops an Experimental Drug to Treat Alzheimer's Disease

52. Following Pain Therapeutic's legal troubles surrounding REMOXY, and the FDA's rejection of REMOXY (after four failed attempts at approval), the Company changed its name to Cassava and shifted its primary focus to continuing to develop therapies to treat Alzheimer's disease.

53. Alzheimer's is a degenerative disease of the brain that affects cognition, function, and behavior. It is the most common cause of dementia. The disease progresses from mild to moderate to, eventually, severe Alzheimer's disease. As it progresses to advanced stages of the disease, cognitive decline becomes more pronounced and more difficult to treat.

54. According to an annual report released by the Alzheimer's Association on Alzheimer's disease facts and figures, in 2025, an estimated 7.2 million Americans aged 65 and older are living with Alzheimer's dementia (*i.e.*, dementia believed to be caused by Alzheimer's disease based on clinical symptoms only).

55. Prior to the Class Period, the Company began developing in-house an oral small molecule drug candidate with a new approach to treat Alzheimer's disease and other neurological disorders, simufilam. During the Class Period, simufilam was Cassava's leading therapeutic candidate for oral treatment of mild to moderate Alzheimer's disease. It was also the Company's only therapeutic drug candidate during the Class Period.

56. Simufilam targets an altered form of a protein called filamin A (“FLNA”) in the Alzheimer’s brain. FLNA is found in high levels in the brain and an altered form of FLNA protein is found in the Alzheimer’s brain. Cassava’s experimental evidence showed that altered FLNA contributes to Alzheimer’s disease by disrupting normal neurons, leading to neurodegeneration and brain inflammation. Simufilam was designed to counter the altered form of FLNA in the brain and restore FLNA’s normal function.

57. The science underlying simufilam was initially published in *The Journal of Neuroscience* in July 2012 in an article authored by, *inter alia*, Dr. Wang, Cassava’s primary scientific consultant, and Burns.

58. In 2015, the Company began pre-clinical studies for simufilam after being awarded a grant by the NIH’s National Institute on Aging. The Company completed those pre-clinical studies in 2017, then submitted an Investigational New Drug (“IND”) application, which was accepted.

59. In October 2017, the Company completed a Phase 1 clinical study for simufilam, which investigated the safety, dosing, and pharmacokinetic profile of simufilam in healthy human volunteers.

60. Then, in 2018, the Company initiated a Phase 2 clinical program in patients with Alzheimer’s disease using simufilam. The Phase 2 clinical program included three studies:

61. First, the Company completed the small, clinical-proof-of-concept, open-label Phase 2a Study in 2019, which enrolled 13 patients and lasted 28 days. The Phase 2a Study suggested improvements in certain key biomarkers of Alzheimer’s pathology, neurodegeneration, and neuroinflammation after treatment with simufilam for 28 days. Biomarker effects were seen

in all patients in both CSF and plasma. The Company touted the fact that no other drug candidate had improved an entire panel of biomarkers in patients with Alzheimer's disease.

62. Second, the Company then began the confirmatory, randomized, placebo-controlled Phase 2b Study in March 2020 which enrolled 64 patients and lasted 28 days. The Company announced the results of the Phase 2b Study in September 2020. Initial reports from the Company suggested that in the Phase 2b Study, patients treated with 50mg or 100mg of simufilam twice-daily showed statistically significant improvements in CSF biomarkers of disease pathology, neurodegeneration, and neuroinflammation and showed improvements in validated tests of episodic memory and spatial working memory (*i.e.*, assessments of cognitive faculties), versus Alzheimer's patients who took placebo. However, as discussed further below, the results of the Phase 2b Study were later called into question for alleged data manipulation and research misconduct by Dr. Wang, the longtime Cassava consultant who performed the final analysis of the CSF samples for the Phase 2b Study after the first lab to conduct the CSF analysis found the study did not meet its primary endpoint.

63. Third, the Company, meanwhile, had also initiated the Phase 2 Study to evaluate simufilam in patients with Alzheimer's disease in March 2020. The Phase 2 Study, which was originally intended to monitor the long-term safety and tolerability of simufilam 100mg twice daily for 12 months in an intended population of 100 patients, was revised to include a 6-month randomized withdrawal period followed by a 6-month open-label period, and the intended population was increased to 200 patients. The Phase 2 Study used the Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-Cog") to measure changes in cognition and the Neuropsychiatric Inventory ("NPI") to assess dementia-related behavior, both standard clinical tools in trials of Alzheimer's disease. Ultimately, the Phase 2 Study had 219 participants and lasted

24 months. It was completed in November 2023 and the Company announced the results in February 2024, but did not publish the full results on ClinicalTrials.gov until February 12, 2025.

64. On February 22, 2021, the Company announced it had completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (“FDA”) for simufilam, during which the Company and the FDA agreed on key elements of a Phase 3 clinical program in support of a New Drug Application (“NDA”) filing for simufilam in Alzheimer’s disease. At that time, only the Phase 2a and Phase 2b studies had been completed. The Company and the FDA agreed that the co-primary endpoints of efficacy would be separate clinical scales to assess cognition (ADAS-Cog) and function (Alzheimer’s Disease Cooperative Study – Activities of Daily Living subscale (“ADCS-ADL”)), and a secondary efficacy endpoint would be a clinical scale that combines cognition and function, such as the integrated Alzheimer’s Disease Rating Scale.

65. On August 24, 2021, Cassava reached an agreement with the FDA under Special Protocol Assessment (“SPA”) for the Phase 3 studies. The FDA concurred with the adequacy and acceptability of specific critical elements of the overall protocol design—such as entry criteria, dose selection, and endpoints—which ensure that the studies can be considered adequate and well-controlled in support of a future regulatory submission and marketing application.

Cassava Faces Scrutiny for Alleged Research Misconduct and Data Manipulation

66. On the same day that the Company and the FDA agreed to the SPA for the Phase 3 studies, after the close of trading, reports emerged that the FDA had received a citizen petition requesting that the FDA halt any future Phase 3 trials of simufilam pending an audit.

67. The citizen petition raised concerns about data and analyses in the foundational research papers authored by Dr. Wang and Burns, which were used to obtain NIH grants and to open an IND application to study simufilam. It alleged there were anomalies in images of tests known as western blots—a common laboratory technique for detecting proteins in samples of

tissue or blood—suggestive of data manipulation. The citizen petition also called into question clinical biomarker data from the Phase 2b Study insofar as the CSF samples were first analyzed by an outside lab, which found that simufilam was ineffective in improving the primary biomarkers endpoint, but when Cassava had the samples analyzed again, the Company reported that simufilam had improved a wide array of biomarkers.

68. An August 30, 2021 supplement to the citizen petition revealed that the re-analysis of CSF samples during the Phase 2b Study had been conducted by Dr. Wang, the longtime Cassava consultant who had a financial interest in simufilam’s success.

69. Additional supplements to the citizen petition were filed on September 9, 2021, November 17, 2021, and December 9, 2021. The initial citizen petition and the supplements thereto are collectively referred to herein as the “Citizen Petition.”

70. Meanwhile, on August 27, 2021, Cassava was sued for securities fraud related to the allegations raised in the Citizen Petition. That litigation is currently pending in this Judicial District under the case caption, *In re Cassava Sciences, Inc. Securities Litigation*, No. 1:21-cv-00751-DAE.

71. On February 10, 2022, the FDA denied the Citizen Petition and its four supplements, stating the denial was “solely on the grounds that [the] requests are not the appropriate subject of a citizen petition.”

72. Nevertheless, multiple government agencies had already begun investigating the Cassava related to the allegations raised in the Citizen Petition.

73. In Cassava’s Q3 2021 quarterly report filed with the SEC on Form 10-Q on November 15, 2021, the Company made a vague disclosure about investigations by undisclosed government agencies:

Certain government agencies have asked us to provide them with corporate information and documents. We have been cooperating and will continue to cooperate with government authorities. No government agency has informed us that any wrongdoing has occurred by any party. We cannot predict the outcome or impact of any of these ongoing matters, including whether a government agency may pursue an enforcement action against us or others.

74. A couple days later, on November 17, 2021, the *Wall Street Journal* reported that the SEC was investigating allegations that Cassava, the sixth-best performing U.S. stock that year, had manipulated research results for simufilam. The article reported that, according to then-CEO Barbier, the NIH, which had awarded \$20 million in grants to Cassava and its academic collaborators since 2015 for drug development, was also examining the claims.

75. On July 27, 2022, *Reuters* reported that the DOJ had opened a criminal investigation into whether Cassava had manipulated research results for simufilam. Cassava submitted a statement for the article through its attorney denying any allegations of wrongdoing but disclosing that Cassava had received confidential requests for information from government agencies, which it refused to identify.

76. On that same day, Cassava issued a press release titled “Cassava Sciences Responds to Media Reports,” stating that the Company “reiterated today what it had previously disclosed in 2021, that certain government agencies had requested information from the Company.” The press released elaborated that “All government requests for information were made in response to allegations of research misconduct that were made in 2021 by financially motivated short-sellers of the Company’s stock.” However, it did not identify which government agencies had requested information from the Company.

77. In September 2022, the FDA conducted an onsite inspection of Dr. Wang’s laboratory at CUNY related to the Phase 2b Study. The FDA identified various deficiencies in the study that were observed during the inspection, including, *inter alia*, Dr. Wang’s laboratory had

“inadequate source records to reconstruct the study” (*i.e.*, failed to maintain documentation of “sample storage and tracking,” documentation of “experimental procedures,” and “[s]ource records for Western blot analysis”); Dr. Wang failed to conduct any stability assessment to support the sample shipment storage and handling conditions for the CSF samples in the study; and there was no access control (*i.e.*, user log-in requirements with passwords) to computers to ensure data security. The FDA inspection report indicated that the DOJ had begun an investigation and had taken files from Dr. Wang’s lab, as well as his computer.

78. Between April and September 2022, Cassava also conducted its own audit of Dr. Wang’s laboratory at CUNY related to his work on the Phase 2b Study, finding that it “was unacceptable and temporarily not qualified to provide biomarker analysis and research for services for any future Cassava studies.” However, Cassava did not disclose the audit’s findings to investors. Cassava also did not sever ties with Dr. Wang until June 2024.

79. CUNY likewise investigated Dr. Wang. On October 12, 2023, the journal *Science* reported that it had obtained a 50-page “Final” report from CUNY, which an anonymous source leaked, detailing CUNY’s investigation of Dr. Wang between fall of 2021 and May 2023 (the “CUNY Report”). According to the CUNY Report, a committee of research-active faculty at CUNY had been tasked with examining thirty-one allegations of research misconduct against Dr. Wang. The committee “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang for 14 of the 31 allegations,” including, *inter alia*, “image aberrations that may be consistent with the fabrication/manipulation of the data,” but they “were unable to objectively assess the merit of the allegations due to the failure of Dr. Wang to provide underlying, original data or research records and the low quality of the published images that had to be examined in their place.” The committee also found “long-standing and egregious misconduct in data

management and record keeping by Dr. Wang” and found that Burns bore some responsibility for some of the alleged misconduct.

80. Cassava released a statement after the market closed on October 12, 2023, rejecting both the validity of the CUNY Report and the CUNY Report’s findings, stating:

Cassava Sciences played no role in CUNY’s investigation. The university turned down all requests for information and offers of assistance from Cassava. Because CUNY did not interview any employees of Cassava Sciences, the university has no legitimate basis to make accusations against the Company or its employees.

CUNY has not responded to an inquiry from Cassava Sciences made yesterday regarding the authenticity of the leaked report.

81. On October 27, 2023, CUNY publicly responded, stating: “Consistent with its policy, CUNY will not comment on the accuracy of the investigation referenced in the articles because no final action as to this investigation has been taken.” CUNY continued: “Because questions regarding the confidentiality and integrity of this investigation have been raised, CUNY will stay the underlying inquiry into the allegations regarding Dr. Wang’s research until such time as the University completes a comprehensive investigation of the process.”

Cassava Misleads Investors about the Investigations into Research Misconduct and Continues to Tout the Tainted Phase 2b Study Results

82. Notwithstanding Defendants’ awareness of the extensive internal and external investigations into research misconduct during the Phase 2b Study, as well as the evidence of research misconduct that had already been uncovered, during the Class Period, Defendants continued to downplay the allegations of research misconduct, mislead investors about the ongoing and past investigations into research misconduct, and tout the controversial Phase 2b Study results in an effort to make simufilam’s prospects appear more favorable.

83. For example, as detailed further below, the Company suggested that there was no evidence of *any* research misconduct by disclosing that “certain government agencies had asked

the Company to provide corporate information and documents,” but “[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors,” and that an internal investigation by Orrick had “found no evidence to substantiate the allegations that *the Company or its employees* engaged in or were aware of research misconduct” (emphasis added).

84. However, by that time, Defendants were aware, or should have been aware absent severe recklessness, of the evidence supporting that there had been research misconduct, including the Company’s *audit of Dr. Wang’s laboratory related to his work on the Phase 2b Study, which found it was “unacceptable and temporarily not qualified to provide biomarker analysis and research for services for any future Cassava studies”* (emphasis added). Further, the leaked CUNY Report “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang for 14 of the 31 allegations” and found that Burns bore some responsibility for the research misconduct. Any reasonable investigation into the allegations contained in the leaked CUNY Report would have revealed Burns’ role in the alleged research misconduct, including that she emailed Dr. Wang a document on May 14, 2020 that enabled him to unblind himself as to some Phase 2b Study participants before he conducted the final analysis and that Burns, herself, had removed a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded.

85. Nevertheless, the Company continued to tout the Phase 2b Study results, including, for example, during a conference in Lisbon, Portugal in March 2024, presenting the “[e]ncouraging effects on cognition” observed during the Phase 2b Study, as well as “improvements in CSF biomarkers of disease pathology, neurodegeneration, and neuroinflammation” and “improvements in validated tests of episodic memory and spatial working memory” versus patients on placebo.

86. However, the truth about the research misconduct during the Phase 2b Study began to come to light on June 28, 2024, when a federal grand jury indicted Dr. Wang for falsifying data to obtain grants from the NIH. The truth continued to trickle out on July 1, 2024, when the Company disclosed that the DOJ and SEC had been investigating Cassava and two senior employees related to the Phase 2b Study, the Company had conducted an internal investigation, and the Company possessed the email from Burns to Dr. Wang that enabled him to unblind himself as to some study participants before conducting the final analysis for the Phase 2b Study.

87. Nevertheless, the Company still did not disclose that the two senior employees involved were Barbier and Burns. The Company also remained silent on their involvement when, on July 17, 2024, while touting the Company's commitment to transparency, the Company announced that Barbier had resigned and that Burns and the Company agreed that she would be leaving the Company effective immediately.

88. A few weeks later, on August 8, 2024, the Company admitted that it was in advanced discussions with the SEC to resolve the SEC's investigation and had set aside \$40 million for potential settlement. The Company also finally walked back its positive statements about the Phase 2b Study results, warning investors to "not place undue reliance" on them.

89. However, it was not until September 26, 2024 that the full truth about the extent of the research misconduct and who was involved came to light when the SEC filed a complaint against Cassava, Barbier, and Burns, alleging, *inter alia*, Burns' involvement in the research misconduct and Barbier's failure to disclose the findings of Cassava's audit of Dr. Wang's laboratory.

The Company Pushes Forward with Simufilam

90. Meanwhile, even as the Company faced scrutiny over the Phase 2b Study, the Company proceeded with its plans to conduct its Phase 3 clinical trials, having initiated two

randomized placebo-controlled Phase 3 studies of simufilam—RETHINK-ALZ and REFOCUS-ALZ.

91. Notably, the only bases for moving forward with the Phase 3 studies were the results from the 13-patient, 28-day Phase 2A trial and the Phase 2b Study, which, in addition to being embroiled in controversy about alleged research misconduct and data manipulation, was likewise brief (28 days) and relatively small (64 patients). The Phase 2 Study was not yet complete when the Company moved forward with the Phase 3 studies.

92. RETHINK-ALZ was designed to evaluate the safety and efficacy of simufilam 100 mg tablets versus placebo over 52 weeks in a multi-center, double-blinded, placebo-controlled, randomized parallel group study involving over 75 clinical trial sites in the United States, Canada, and Australia. The trial randomized 804 people with confirmed mild or moderate Alzheimer's disease.

93. The primary objective of the RETHINK-ALZ study was to investigate the safety and efficacy of simufilam in enhancing cognition and slowing cognitive and functional decline in participants with mild-to-moderate Alzheimer's disease from baseline to the end of the double-blind treatment period at week 52, as assessed by the ADAS-COG and ADCS-ADL scales, comparing simufilam to placebo. Secondary and tertiary objectives included assessing the drug's effect on neuropsychiatric symptoms and caregiver burden and investigating the effect of simufilam treatment on plasma biomarkers. The study also included a pharmacokinetic and plasma biomarker sub-study comprised of approximately 100 subjects, evaluated at three timepoints.

94. An Independent Data Safety Monitoring Board met periodically to review subject safety assessments and determined that dosing could continue.

95. REFOCUS-ALZ was designed as a multi-center, double-blinded, placebo-controlled, randomized parallel group study to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg tablets versus placebo over 76 weeks. The study involved over 75 clinical trial sites in the United States, Canada, Puerto Rico, and South Korea, which were completely distinct from the clinical trial sites that conducted RETHINK-ALZ. The trial randomized approximately 1,125 people utilizing the same eligibility criteria as RETHINK-ALZ.

96. The co-primary endpoints of the REFOCUS-ALZ trial included the change in cognition and function from baseline to the end of the double-blind treatment period at week 76, assessed by the ADAS-COG and ADCS-ADL scales, comparing simufilam to placebo. Secondary endpoints included neuropsychiatric symptoms and caregiver burden. The study also included an evaluation of changes in plasma and CSF biomarkers from baseline to week 76, as well as tests involving magnetic resonance imaging and positron emission tomography scans.

97. The Company completed patient enrollment in the RETHINK-ALZ and REFOCUS-ALZ Phase 3 clinical trials in November 2023, enrolling approximately 1,900 patients with mild to moderate Alzheimer's disease. Approximately 70% of those patients had mild Alzheimer's disease.

98. The Company also initiated an open-label extension study for the Phase 3 program to provide no-cost access to simufilam for 36 months, or until a new drug application for simufilam has been reviewed by the FDA, to Alzheimer's patients who successfully completed a Phase 3 study of simufilam and opted to participate. Approximately 88% of patients who completed treatment in one of the two Phase 3 studies opted to enter the open-label extension study.

Defendants Mislead Investors About the Phase 2 Study Results to Make Simufilam's Progress and Potential Appear More Favorable

99. While the Phase 3 trials were ongoing, the Company reported the topline results for the Phase 2 Study in a February 7, 2024 press release titled “No Decline in Cognition Scores in Patients with Mild Alzheimer’s Disease Who Received Simufilam Continuously For 24 Months.” The press release stated that:

- Patients with mild Alzheimer’s disease who received simufilam treatment continuously for two years . . . had no decline in ADAS-Cog scores . . . as a group.
- Patients with mild Alzheimer’s who received simufilam treatment non-continuously . . . declined 1 point on ADAS-Cog . . . as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer’s, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer’s who received simufilam treatment continuously for two years . . . declined 11.05 points on ADAS-Cog . . . as a group.

100. The Company’s 2023 annual report and quarterly reports for Q1 2024 through Q3 2024 likewise included summaries of the Phase 2 Study results.

101. Nevertheless, as explained further below, Defendants’ descriptions of the Phase 2 Study results were misleading for two reasons. First, the results were based on an analysis of only roughly half of the ITT population, *i.e.*, all randomized patients, regardless of treatment. Second, patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends.

A. Defendants Mislead the Public about the Patient Population Analyzed in the Phase 2 Study Results

102. The Phase 2 Study had an ITT population of 219 patients. However, Defendants failed to disclose that only 116 patients were analyzed for the Phase 2 Study results, roughly 53% of the ITT population. That information did not come to light until long *after* Defendants' misleading statements about the Phase 2 Results were made, when the Phase 2 Study results were posted on ClinicalTrials.gov on February 12, 2025.

103. Defendants also misrepresented the patient population that was analyzed for the Phase 2 Study in the Company's 2023 annual report and Q1 2024 through Q3 2024 quarterly reports, stating:

The pre-specified cognition endpoints were analyzed on the Full Analysis Set (FAS) by an independent consulting firm that specializes in complex statistical analysis of clinical trial results. ***The FAS population consists of all study participants who received at least one dose of treatment and have both baseline and at least one post-baseline assessment.*** (Because FAS data is specific to each phase of a study, the FAS for the 24-month study may differ from the FAS for other study phases).

(Emphasis added).

104. According to the ICH E9 Statistical Principles for Clinical trials, a document that provides guidance on the analysis of clinical trials and is adopted as official policy by the FDA, the FAS is "used to describe the analysis set which is . . . ***as close as possible to the intention-to-treat ideal of including all randomized subjects***" (emphasis added). (ITT analysis, which includes all patients who are randomized in the statistical analysis, preserves the benefits of randomization because excluding patients from the analysis who did not get their intended treatment increases the risk of bias and can impact the results.)

105. While the description of the FAS population contained in the Company's 2023 annual report and Q1 2024 through Q3 2024 quarterly reports was consistent with ICH E9

standards, the Company ultimately did not apply that definition and defined the FAS population differently when it analyzed patients at the end of the Phase 2 Study.

106. Specifically, the Phase 2 Study results posted on ClinicalTrials.gov indicate that the nominally FAS population actually analyzed for the Phase 2 Study consisted of those patients who completed an ADAS-Cog-11 assessment at baseline *and month 24*. Thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed.

107. This substantial change was significant because it ultimately resulted in only roughly half of the ITT population being analyzed and, because it excluded patients who dropped out of the study before completion, the results may have been biased towards those patients who were, or who were perceived to be, benefitting from treatment.

108. In addition, the change was significant because the revised method for determining the FAS population violated ICH E9 standards, which provide that FAS should be as close as possible to the ITT analysis because “[p]reservation of the initial randomization in analysis is important in preventing bias and in providing a secure foundation for statistical tests.”

109. ICH E9 only allows for the exclusion of patients from the FAS population for three reasons: “the failure to satisfy major entry criteria (eligibility violations), the failure to take at least one dose of trial medication[,] and the lack of any data post randomization.” Critically, patients who opt to discontinue during the course of the trial, such as those patients the Company excluded from the FAS population for the Phase 2 Study results, are not included in any of the permissible exceptions. Despite ICH E9’s prohibition against excluding patients for other reasons, the Company nonetheless excluded patients who discontinued during the course of the study.

110. The Company's use of a non-standard method for calculating the FAS population was also significant because in the later Phase 3 RETHINK-ALZ trial, the Company relied on the more rigorous, ITT analysis which included "all randomized patients." Thus, there were inherent limitations in the predictive power of the Phase 2 Study results for the Phase 3 trials, especially given that Defendants did not disclose that there would be a progression in the analysis from the non-standard and ICH E9 noncompliant FAS population during the Phase 2 Study to the more rigorous ITT population during the Phase 3 trials.

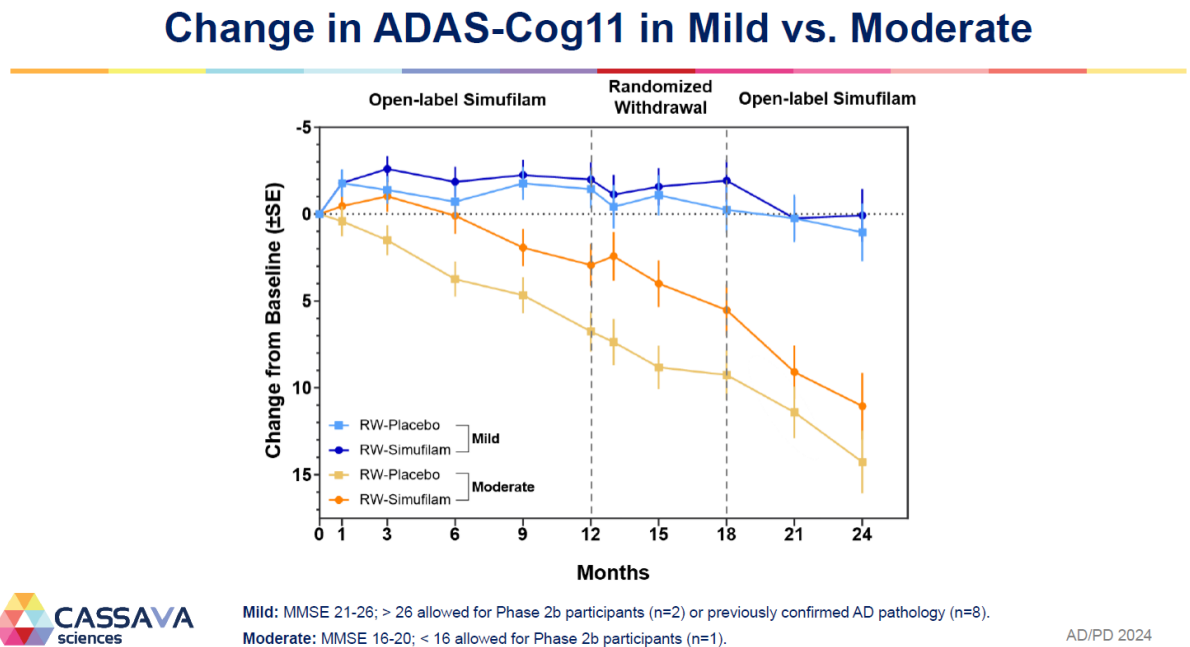
B. Defendants Make Material Misrepresentations Regarding the Phase 2 Study Results

111. In addition to misrepresenting the Phase 2 Study results based on the patient population analyzed, Defendants also misrepresented the Phase 2 Study results as "remarkable" when patients with mild Alzheimer's disease performed similarly whether they were on simufilam or placebo, with no consistent trends. Thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer's disease population was inconclusive and any takeaways drawn from how the mild Alzheimer's disease population performed heavily depended on the period of the Phase 2 Study examined. For example, the largest separation (1.2 points on the ADAS-Cog scale) in performance in mild Alzheimer's disease patients on placebo versus on active treatment occurred at the end of the 6-month randomized withdrawal trial (*i.e.*, at month 18), the end of the portion of the trial when some patients remained on active treatment while others were on placebo. Viewed in isolation, that might be a positive finding for simufilam, but this ignores that in the prior measurement – after being off simufilam for three months – patients in the placebo arm showed positive improvement and converged with the simufilam arm such that the separation was only 0.2 points on the ADAS-Cog scale.

112. Similarly, placebo patients showed declining performance at both three and six months *after resuming simufilam therapy*. Indeed, even mild patients who were on simufilam without interruption declined in the last six months and were superior to placebo at the end of the trial because the latter group continued to decline after resuming therapy. Had the trial ended just three months earlier, there would have been no discernible difference between the two arms.

113. The following chart, which Defendants included in certain public filings and presentations (but not in the February 7, 2024 press release announcing end-of-trial results), is illustrative:

:



114. Thus, the overall takeaway from the Phase 2 Study results as to how the drug performed in patients who received continuous treatment versus non-continuous treatment was inconclusive, and certainly not the overly optimistic “remarkable” results that Defendants led investors to believe.

115. Nevertheless, Defendants spun the Phase 2 Study results to make them appear more favorable than they were. For example, during a fireside chat at the H.C. Wainwright 26th Annual Global Investment Conference, held in New York City on September 9-11, 2024, Barry stated “what we’ve seen so far, phase 2 results is, this to me was, you know, very impressive and one of the reasons I’m here” insofar as “*at the end of 2 years the mild patients in the trial showed virtually no cognition decline*” and “that is unheard of” and “nobody has seen results like that before.” Kupiec later expressed his excitement and optimism about simufilam’s outlook for success during the Phase 3 trial based on the “remarkable” data from the Phase 2 Study.

Defendants’ Motivation to Mislead Investors

116. Defendants were motivated to mislead investors about the tainted Phase 2b Study, the investigations related thereto, and the Phase 2 Study results in order to make simufilam’s prospects appear better and garner support for the drug’s continued development because (a) the Company needed to raise additional capital, and (b) simufilam was the Company’s sole therapeutic drug candidate, the Company did not generate any revenue, and its financial success was dependent on the successful development of simufilam for commercial sale.

117. On January 3, 2024, the Company distributed warrants to shareholders of record as of December 22, 2023 in an effort to raise capital to support the ongoing Phase 3 clinical trials. Between January 3, 2024 and February 26, 2024—a time period during which Defendants continued to mislead investors about the tainted Phase 2b Study, the investigations related thereto, and the Phase 2 Study results in order to make simufilam’s prospects appear more favorable—the Company received gross proceeds of approximately \$21.8 million from the exercise of warrants.

Simufilam Fails to Meet the Phase 3 Endpoints

118. The previously undisclosed risk that Defendants had misleadingly presented the Phase 2 Study results to make simufilam's prospects appear more favorable began to materialize when the Company announced that the Phase 3 studies had failed.

119. On November 25, 2024, Cassava announced the topline results from the Phase 3 RETHINK-ALZ study, reporting that simufilam did not meet the pre-specified co-primary, secondary, and exploratory biomarker endpoints. Given the results, the Company announced that it would be discontinuing the Phase 3 REFOCUS-ALZ study and open-label extension study.

120. In a March 3, 2025 press release titled "Cassava Sciences Reports 2024 Financial Results and Provides Business Update," Barry informed investors:

Cassava is preparing to report the topline results of the now-discontinued REFOCUS-ALZ, the second Phase 3 study of simufilam in Alzheimer's disease, in late first-quarter/early-second quarter 2025. ***We intend to evaluate the next steps for simufilam in Alzheimer's disease after reviewing the REFOCUS-ALZ results in conjunction with the results of the RETHINK-ALZ study,*** reported in November 2024, which did not meet the prespecified co-primary endpoints.

(Emphasis added).

121. On March 25, 2025, in a press release titled "Cassava Sciences Reports Topline Phase 3 REFOCUS-ALZ Data," the Company reported that "[s]imufilam did not show a significant reduction in co-primary endpoints of cognitive or functional decline versus placebo in patients with mild-to-moderate Alzheimer's disease."

DEFENDANTS MADE MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD, WHICH WAS REVEALED IN A SERIES OF CORRECTIVE DISCLOSURES AND WHEN THE PREVIOUSLY UNDISCLOSED RISK MATERIALIZED

122. As detailed further below, throughout the Class Period, Defendants made two categories of misleading misstatements. *First*, notwithstanding their awareness of the internal and external investigations into the alleged research misconduct during the Phase 2b Study, as well as

the evidence of research misconduct that had already been uncovered, Defendants continued to deny or otherwise downplay the allegations of research misconduct during the Phase 2b Study, and the investigations related thereto, and tout the Phase 2b Study results. *Second*, Defendants also misled investors about the Phase 2 Study results. Both of these categories of misstatements were designed to make simufilam's progress and potential appear more favorable to the public.

The Tainted Phase 2b Study and the Related Investigations

A. Defendants Made Materially False and Misleading Statements About the Tainted Phase 2b Study and the Related Investigations

123. On October 12, 2023, the Company issued a response to the CUNY Report allegations, quoting Barbier and listing Schoen as the individual to contact for more information. The response attempted to downplay and undermine the validity of the CUNY investigation results, including the CUNY Report findings that there was "evidence highly suggestive of deliberate scientific misconduct by Dr. Wang" and that Burns bore some responsibility for the alleged misconduct. The October 12, 2023 response stated in relevant part:

CUNY's report makes no findings of data manipulation. Rather, "the egregious misconduct" cited in the report relates exclusively to internal record-keeping failures at CUNY. The report also finds that internal record-keeping failures "prevented [CUNY] from making an objective assessment" of the allegations of research misconduct.

[...]

Cassava Sciences played no role in CUNY's investigation. The university turned down all requests for information and offers of assistance from Cassava. Because CUNY did not interview any employee of Cassava Sciences, the university has no legitimate basis on which to make accusations of the allegations of research misconduct.

CUNY has not responded to an inquiry Cassava Sciences made yesterday regarding the authenticity of the leaked report.

Importantly, Cassava Sciences does not rely exclusively on research at CUNY.

124. This statement was false or misleading because it (a) misleadingly suggested there was no evidence to support that Dr. Wang had engaged in research misconduct when the Company had already completed an audit of Dr. Wang’s laboratory related to his work on the Phase 2b Study and found that it was “unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies;” (b) misleadingly suggested the CUNY Report’s finding that Burns bore some responsibility for the research misconduct was unfounded when Burns was involved—i.e., by, *inter alia*, emailing Dr. Wang a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis and by removing a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded—which Barbier, Schoen, and the Company knew or should have known had they conducted any reasonable investigation before causing the Company to deny the findings in the CUNY Report; and (c) misleadingly downplayed the significance of CUNY’s role in the Company’s simufilam research when the Phase 2b Study Results were derived from Dr. Wang’s final analysis of the CSF samples at his CUNY laboratory, notably, after another laboratory had already conducted an analysis and found that the study did not meet its primary endpoint.

125. The Company’s Q3 2023 quarterly report filed with the SEC on a Form 10-Q on November 7, 2023 (the “Q3 2023 10-Q”)—which Barbier and Schoen signed—downplayed the government investigations that had been ongoing since 2021:

On November 15, 2021, the Company disclosed that certain government agencies had asked the Company to provide corporate information and documents. These were confidential requests. The Company has been voluntarily cooperating and intends to continue to cooperate with these inquiries. ***No government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees or directors.*** No government agency has filed any claims or charges related to these inquiries. We cannot predict the outcome or impact of these ongoing matters, including whether

a government agency may pursue an enforcement action against the Company or others.

(Emphasis added).

126. After the Company filed the Q3 2023 10-Q, Cassava’s stock price rose about 4.3%, closing at \$22.30 per share on November 7, 2023 after closing at \$21.38 per share on November 6, 2023.

127. The Company’s 2023 annual report filed with the SEC on a Form 10-K on February 28, 2024 (the “2023 Annual Report”)—which was signed by, *inter alia*, Barbier, Schoen, and Barry—contained a similar disclosure:

On November 15, 2021, we disclosed that certain government agencies had asked us to provide corporate information and documents. These were confidential requests. We have been voluntarily cooperating and intend to continue to cooperate with these inquiries. ***No government agency has informed us that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors.*** No government agency has filed any claims or charges related to these inquiries. We cannot predict the outcome or impact of these ongoing matters, including whether a government agency may pursue an enforcement action against the Company or others.

(Emphasis added).

128. The statements set forth in ¶¶125 and 127 were false or misleading because (a) they misleadingly suggested there was no evidence of *any* research misconduct by artfully stating “[n]o government agency has informed [the Company] that it has found evidence of research misconduct or wrongdoing by ***the Company or its officers, employees, or directors***” (emphasis added), intentionally omitting the Company’s third-party collaborators, such as Dr. Wang, because the Company’s own audit of Dr. Wang’s laboratory at CUNY related to his work on the Phase 2b Study had found that it was “unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies” and the CUNY Report “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang;” and (b) they

misleadingly suggested there was no evidence of research misconduct by the Company's officers when the Company possessed evidence that Burns was involved (i.e., a May 14, 2020 email from Burns to Dr. Wang attaching a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis) and Burns was otherwise involved in the research misconduct by, *inter alia*, removing a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded—which Barbier, Schoen, and the Company knew or should have known had they conducted any reasonable investigation before causing the Company to deny the findings in the CUNY Report that Burns bore some responsibility for the research misconduct.

129. The 2023 Annual Report also reported that the Company's Board had retained the law firm Orrick to investigate the allegations of research misconduct raised in the Citizen Petition:

Beginning in August 2021, certain individuals, later revealed to be short sellers of the Company's securities, publicly alleged that ***the Company and certain of its employees and third-party collaborators*** had engaged in research misconduct in connection with the development of simufilam. These allegations related in part to research that was conducted at [CUNY] pursuant to research contracts with the Company.

The Company takes allegations of research misconduct seriously. ***Accordingly, the Company's Board of Directors engaged the law firm [Orrick] to investigate these allegations. The investigation had access to Company personnel, communications, documents, data, and information, and counsel was assisted by technical experts with relevant experience and knowledge. The investigation has found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct.***

(Emphasis added).

130. On that same day that it filed the 2023 Annual Report, the Company issued a press release titled "Cassava Reports Full-year 2023 Financial Results and Corporate Updates," which quoted Barbier and Schoen and listed Schoen as the individual to contact for more information. The Company also filed an identical copy of the press release as an exhibit to a Form 8-K filed

with the SEC on February 28, 2024, which Schoen signed. The press release contained the same disclosure as the 2023 Annual Report about Orrick’s internal investigation into research misconduct, set forth in ¶¶129 above. The press release likewise stated: “Today we report that an internal investigation conducted by outside counsel engaged by our Board of Directors has found no evidence to substantiate allegations that the Company or its employees engaged in or were aware of research misconduct.”

131. The statements set forth in ¶¶129-130 were false or misleading because: (a) they disclosed that Orrick had investigated the allegations that the Company *and its third-party collaborators* had engaged in research misconduct, but misleadingly suggested that there was no evidence of *any* research misconduct by artfully stating that there was no “evidence to substantiate the allegations that [just] *the Company or its employees*” were involved, intentionally omitting the Company’s third-party collaborators, such as Dr. Wang, because the Company’s own audit of Dr. Wang’s laboratory at CUNY related to his work on the Phase 2b Study had found that it was “unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies” and the CUNY Report “found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang;” (b) they misleadingly suggested that there was no evidence of research misconduct by the Company’s officers when the Company possessed evidence of Burns’ involvement (i.e., a May 14, 2020 email from Burns to Dr. Wang attaching a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis) and Burns was otherwise involved in the research misconduct by, *inter alia*, removing a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded—which Barbier, Schoen, and the Company knew or should have known had they conducted any reasonable

investigation before causing the Company to deny the findings in the CUNY Report that Burns bore some responsibility for the research misconduct, and which the Orrick investigation should have uncovered.

132. The Company's Q1 2024 quarterly report filed with the SEC on a Form 10-Q on May 10, 2024 (the "Q1 2024 10-Q") and signed by Barbier and Schoen, again downplayed the government investigations that had been ongoing since 2021:

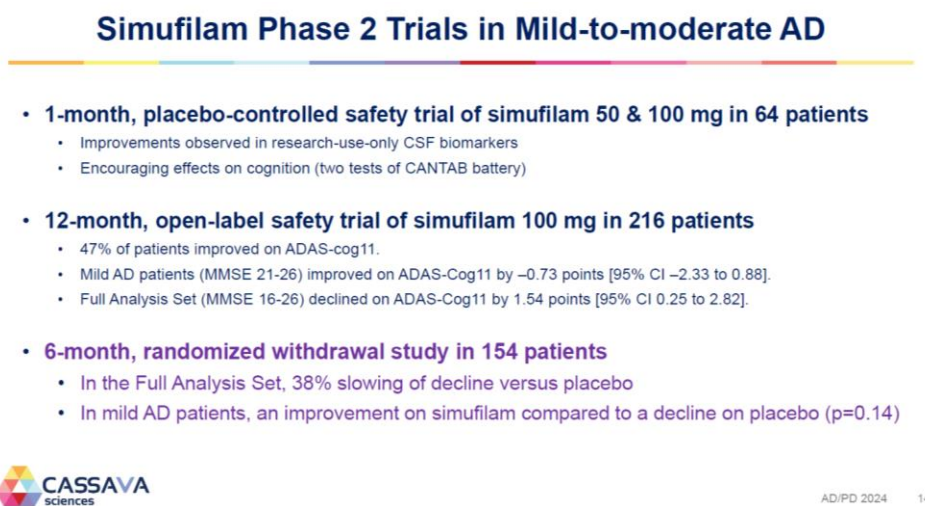
On November 15, 2021, the Company disclosed that certain government agencies had asked the Company to provide corporate information and documents. These were confidential requests. The Company has been voluntarily cooperating and intends to continue to cooperate with these inquiries. *No government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by the Company or its officers, employees, or directors.* No government agency has filed any claims or charges related to these inquiries. We cannot predict the outcome or impact of these ongoing matters, including whether a government agency may pursue an enforcement action against the Company or others.

(Emphasis added).

133. This statement was misleading for the same reasons discussed in ¶128, because (a) it misleadingly suggested there was no evidence of *any* research misconduct by artfully stating "[n]o government agency has informed the Company that it has found evidence of research misconduct or wrongdoing by *the Company or its officers, employees, or directors*" (emphasis added), intentionally omitting the Company's third-party collaborators, such as Dr. Wang, because the Company's own audit of Dr. Wang's laboratory at CUNY related to his work on the Phase 2b Study had found that it was "unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies" and the CUNY Report "found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang;" and (b) it misleadingly suggested there was no evidence of research misconduct by the Company's officers when the Company possessed evidence that Burns was involved (i.e., a May 14, 2020 email from


Burns to Dr. Wang attaching a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis) and Burns was otherwise involved in the research misconduct by, *inter alia*, removing a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded—which Barbier, Schoen, and the Company knew or should have known had they conducted any reasonable investigation before causing the Company to deny the findings in the CUNY Report that Burns bore some responsibility for the research misconduct.

134. Notwithstanding the significant ongoing controversy surrounding the Phase 2b Study, during a presentation at the International Conference on Alzheimer’s and Parkinson’s Disease (AD/PD 2024) in Lisbon, Portugal from March 5-9, 2024, Burns presented the slide below, which touted the Phase 2b Study results, noting in the first bullet point, which pertained to the Phase 2b Study, “[i]mprovements observed in research-use-only CSF biomarkers” and “[e]ncouraging effects on cognition” observed during the Phase 2b Study:



Simufilam Phase 2 Trials in Mild-to-moderate AD

- **1-month, placebo-controlled safety trial of simufilam 50 & 100 mg in 64 patients**
 - Improvements observed in research-use-only CSF biomarkers
 - Encouraging effects on cognition (two tests of CANTAB battery)
- **12-month, open-label safety trial of simufilam 100 mg in 216 patients**
 - 47% of patients improved on ADAS-cog11.
 - Mild AD patients (MMSE 21-26) improved on ADAS-Cog11 by -0.73 points [95% CI -2.33 to 0.88].
 - Full Analysis Set (MMSE 16-26) declined on ADAS-Cog11 by 1.54 points [95% CI 0.25 to 2.82].
- **6-month, randomized withdrawal study in 154 patients**
 - In the Full Analysis Set, 38% slowing of decline versus placebo
 - In mild AD patients, an improvement on simufilam compared to a decline on placebo (p=0.14)

 AD/PD 2024 14

135. Likewise, the Q1 2024 10-Q stated:

In September 2020, we reported final results of a Phase 2b study with simufilam in Alzheimer’s disease. *In this clinical study funded by the NIH, Alzheimer’s patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant . . . improvements in CSF biomarkers of disease*

pathology, neurodegeneration, and neuroinflammation, versus Alzheimer's patients who took placebo. . . . In addition, Alzheimer's patients treated with simufilam showed improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo. . . .

Given the absence of observable dose-limiting effects in our Phase 1 and Phase 2 studies, and in light of the strong scientific rationale and multiple peer-reviewed publications and research grant awards, we determined that simufilam demonstrated favorable proof-of-principle for further evaluation as an investigational drug for the treatment of Alzheimer's disease.

(Emphasis added).

136. The statements set forth in ¶¶134-135 were misleading because they continued to tout the Phase 2b Study results notwithstanding (a) the extensive ongoing investigations into whether Dr. Wang and Cassava employees and executives engaged in research misconduct during the Phase 2b Study; (b) the Company's own audit of Dr. Wang's laboratory at CUNY related to his work on the Phase 2b Study found it was "unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies;" (c) the CUNY Report "found evidence highly suggestive of deliberate scientific misconduct by Dr. Wang" and that Burns bore some responsibility for some of the alleged research misconduct; and (d) the Company possessed evidence of Burns' involvement in the research misconduct (i.e., a May 14, 2020 email from Burns to Dr. Wang attaching a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis) and Burns was otherwise involved in the research misconduct by, *inter alia*, removing a large portion of patients in reported cognition data (which showed no meaningful improvement in patient cognition) after she was unblinded—which Barbier, Schoen, and the Company knew or should have known had they conducted any reasonable investigation before causing the Company to deny the findings in the CUNY Report.

B. The Truth About the Tainted Phase 2b Study and Investigations Related Thereto Began to Emerge, but Defendants Continued to Mislead Investors

137. The truth about the research misconduct during the Phase 2b Study and the scope of the investigations into such research misconduct began to emerge on June 28, 2024, when a federal grand jury indicted Dr. Wang on charges of falsifying data to obtain grants totaling roughly \$16 million from the NIH.

138. The DOJ issued a press release on June 28, 2024, reporting that the indictment alleged that from approximately May 2015 through April 2023, Dr. Wang was “engaged in a scheme to fabricate and falsify scientific data in grant applications made to the NIH on behalf of him and [a publicly traded Texas] biopharmaceutical company,” Cassava, which “sought funding for scientific research of a potential treatment and diagnostic test for Alzheimer’s disease.”

139. Upon this news, Cassava’s stock fell from a closing price of \$18.95 per share on June 27, 2024 to close at \$12.35 per share on June 28, 2024, a decline of about 34.83%.

140. The truth about the research misconduct during the Phase 2b Study and the scope of the investigations related thereto continued to emerge on July 1, 2024, the following business day, when the Company filed a Form 8-K, signed by Schoen, stating:

[Cassava] has been engaging with the [DOJ] and the [SEC] in connection with ongoing investigations into the Company ***and two senior employees of the Company***. Cassava is cooperating with the DOJ and SEC in connection with these investigations.

In the course of ongoing discussions with the SEC regarding the Company’s Phase 2b study of simufilam in Alzheimer’s disease (the “Phase 2b Study”), the SEC recently provided the Company with new information obtained during its investigation. ***The Company’s Board of Directors (the “Board”) has empowered an Ad Hoc Investigation Committee (the “Committee”), comprising independent directors, to direct an investigation (the “Internal Investigation”) of the information provided by the SEC. The Internal Investigation is also evaluating information contained in the DOJ indictment of Dr. Hoau-Yan Wang discussed below.*** This Committee, with the assistance of the Company’s General Counsel, is supervising outside counsel conducting the Internal Investigation. The Internal Investigation is continuing.

(Emphasis added).

141. The July 1, 2024 8-K also revealed that “*the Internal Investigation has determined that certain statistical information contained in an attachment to an email sent by a senior employee of Cassava to Dr. Wang before the bioanalysis could have been used to unblind him as to some number of Phase 2b Study participants*” (emphasis added).

142. Upon this news, the Company’s stock declined even further, falling from a closing price of \$12.35 per share on June 28, 2024 to close at \$12.14 per share on July 1, 2024.

143. However, Defendants continued to mislead investors about the Company’s executives’ involvement in the research misconduct.

144. On July 17, 2024, the Company announced Barbier’s resignation and the termination of Burns’ employment, effective immediately, in a Form 8-K signed by Schoen, which attached a press release titled “Cassava Sciences Announces Changes in Executive Leadership, Enhanced Corporate Governance and Other Initiatives.”

145. The July 17, 2024 Form 8-K indicated that Barbier had resigned, that his resignation had been deemed “Other Than for Cause,” and that “Mr. Barbier’s resignation from the Board [was] not a result of any disagreement with the Company on any matter relating to the Company’s operations, policies or practices.” The July 17, 2024 Form 8-K also reported that Cassava and Burns “agreed that Burns [would] step down from her employment with the Company, effective immediately,” but that Burns would continue to “furnish consulting services” for one year.

146. The press release attached to the July 17, 2024 8-K announced that Barry would be succeeding Barbier and had been appointed as Executive Chairman of the Board and the Company’s principal executive officer.

147. Barry was quoted in that press release touting the Company’s commitment to integrity: “While our priority remains the development of a potentially effective treatment for

Alzheimer’s disease, the Board has a steadfast commitment to doing so with transparency, accountability, and highest ethical business practices.” The press release also highlighted actions that the Company took in furtherance of that, including appointing new leadership, reaffirming the Company’s “single-minded commitment to scientific rigor and honest transparency with patients, government agencies and investors,” emphasizing that the Phase 3 trials were “being run according to FDA and industry standards that ensure the integrity of all reported results,” and promising transparency in communicating with stakeholders.

148. The statements referenced in ¶¶145, 147 were false or misleading because: (a) while emphasizing the Company’s commitment to transparency, accountability, and ethical business practices, they failed to disclose that Barbier’s and Burns’ departure from the Company stemmed from their involvement in the alleged research misconduct related to the Phase 2b Study; and (b) the Company was not being transparent about the research misconduct related to the Phase 2b Study, including that the Company’s 2022 audit had found Dr. Wang’s laboratory at CUNY “unacceptable and temporarily not qualified to provide biomarker analysis and research for any services for any future Cassava studies,” and it was Burns who sent the email that enabled Dr. Wang to unblind himself as to some patients in the Phase 2b Study before he performed the final analysis of CSF samples.

C. The Full Truth About the Tainted Phase 2b Study and Investigations Related Thereto Emerged

149. The extent of the government investigations into the alleged research misconduct and the unreliability of the Phase 2b Study was revealed for the first time on August 8, 2024, when the Company filed its Q2 2024 quarterly report on a Form 10-Q with the SEC (the “Q2 2024 10-Q”), which Barry and Schoen signed, disclosing:

Beginning in August 2021, the Company has received subpoenas, a Civil Investigative Demand (“CID”) and other requests for documents and information

from the Department of Justice and document requests from the Securities and Exchange Commission, each seeking corporate information and documents concerning the research and development of simufilam and/or SavaDX. The Company has been providing documents and information in response to these subpoenas, CID, and requests for information and intends to continue to cooperate with these government inquiries. The Company cannot predict the outcome or impact of these ongoing matters, including whether the government authority may pursue an enforcement action against the Company or others.

The Company is in the advanced stages of discussions with the SEC staff to resolve the SEC's nearly three-year investigation of the Company's disclosures regarding its Phase 2b study of simufilam for the treatment of Alzheimer's disease (the "Phase 2b Study"). The Company has reserved a loss contingency of \$40 million on its consolidated balance sheet as of June 30, 2024 relating to this potential settlement with the SEC.

The Company continues to cooperate with the DOJ related to conduct alleged in the indictment of Dr. Hoau-Yan Wang announced by the Department of Justice on June 28, 2024.

(Emphasis added).

150. The Q2 2024 10-Q also provided more information about Dr. Wang's indictment, while attempting to distance the Company from Dr. Wang by pointing out his lack of involvement with the Phase 3 studies:

On June 28, 2024, the DOJ announced that a federal grand jury in the U.S. District Court for the District of Maryland returned an indictment of Dr. Wang. The indictment alleges that Dr. Wang caused Cassava to submit grant applications to the [NIH] that contained false and fraudulent representations about his research. Among other things, the indictment alleges that Dr. Wang made materially false, fraudulent, and misleading statements to the NIH regarding the mechanism by which the Company's therapeutic product candidate, simufilam, was designed to treat Alzheimer's disease and the improvement of certain Alzheimer's disease indicators in patients treated with simufilam, and that Dr. Wang manipulated or otherwise fabricated research results, including Western Blot images that he prepared.

Dr. Wang, who is employed as a professor at [CUNY], previously served as a scientific collaborator and advisor to Cassava. Dr. Wang's research, including foundational research published together with Dr. Lindsay Burns, Cassava's former SVP, Neuroscience, led to the discovery of simufilam. Among other work for Cassava, Dr. Wang's laboratory at CUNY conducted the final bioanalysis for the Phase 2b Study, which the Company reported as part of the final results of the Phase 2b Study.

Dr. Wang received compensation from the Company for his consulting and advisory work for Cassava. . . . Prior to Dr. Wang's indictment, the Company terminated its consulting relationship with him

Neither Dr. Wang nor his laboratory at CUNY has had any involvement at any time in the Company's ongoing Phase 3 clinical trials of simufilam.

(Emphasis added).

151. For the first time, Defendants also warned investors to “not place undue reliance” on the Phase 2b Study results. The risk factors section of the Q2 2024 10-Q, under the heading “The validity of CSF biomarker assays and bioanalysis conducted by CUNY for the Company's Phase 2b Study has been called into question,” warned in relevant part:

The Company's Phase 2b Study was designed as a 28-day, approximately 60-patient, randomized, double-blind, placebo-controlled, multiple dose study. A primary objective of the Phase 2b Study was to measure changes in levels of cerebral spinal fluid (“CSF”) biomarkers in study participants from baseline value to Day 28. ***CSF biomarker assays and related bioanalysis for the Phase 2b Study (the “CUNY Bioanalysis”) were conducted by the laboratory at CUNY of Dr. Hou-Yan Wang, formerly a paid scientific collaborator, consultant and advisor to Cassava. Based on the CUNY Bioanalysis, Cassava reported statistically significant improvements in CSF biomarkers in treatment groups as compared to placebo group for the Phase 2b Study.***

On June 28, 2024, the DOJ announced that a federal grand jury in the U.S. District Court for the District of Maryland returned an indictment of Dr. Wang alleging that he caused Cassava to submit grant applications to NIH that contained false and fraudulent representations about his research. Among other things, the indictment alleges that Dr. Wang made materially false, fraudulent, and misleading statements to NIH regarding the mechanism by which simufilam was designed to treat Alzheimer's disease and the improvement of certain Alzheimer's disease indicators in patients treated with simufilam, ***and that Dr. Wang manipulated or otherwise fabricated research results, including Western Blot images that he prepared.***

As part of the Internal Investigation being conducted by the Ad Hoc Investigation Committee of the Company's Board of Directors, the Committee is evaluating information contained in the DOJ indictment of Dr. Wang as well as information from the Company's ongoing discussions with the SEC. To date, the Internal Investigation has determined that certain statistical information contained in an attachment to an email sent by a former senior employee of Cassava to Dr. Wang before the CUNY Bioanalysis of CSF biomarkers was conducted could have been used to unblind him as to some number of Phase 2b Study participants. Unblinded information, if accessed in connection with bioanalysis, could be

improperly utilized to manipulate underlying samples or data to skew reported results.

The Internal Investigation has not, to date, determined, and may never be able to determine with any reasonable degree of certainty, whether Dr. Wang unblinded himself as to some number of Phase 2b Study participants. ***Nevertheless, the fact that Dr. Wang possessed information that could have been used to so unblind himself, together with the allegations in the DOJ indictment, undermine the blinded study design and create substantial uncertainty about the validity of the CUNY Bioanalysis of CSF biomarkers.*** There can be no assurance that such uncertainty will not adversely impact the FDA's review of an NDA with respect to simufilam following completion of our Phase 3 clinical studies or cause the FDA to request additional information regarding simufilam.

Accordingly, in light of the foregoing uncertainties, you should not place undue reliance on the CUNY Bioanalysis of CSF biomarkers reported by the Company in connection with the Phase 2b Study.

(Emphasis added).

152. Upon this news, Cassava's stock fell from a closing price of \$30.20 per share on August 7, 2024, to close at \$26.02 per share on August 8, 2024, a decline of about 13.84%.

153. Then, on September 26, 2024, after the close of trading, the full truth about the extent of the research misconduct and who was involved was revealed when the SEC filed charges against Cassava, Barbier, and Burns related to their misleading statements about the results of Phase 2b Study and announced that they had agreed to a settlement.

154. The SEC complaint alleged, *inter alia*:

- Cassava's statements about conducting blinded studies negligently omitted the material information that Burns provided Dr. Wang with information sufficient to partially unblind himself during the Phase 2b Study;
- The Company, Barbier, and Burns failed to disclose that the Phase 2b results of the bioanalyses were performed by Dr. Wang, and Dr. Wang had conflicts of interest due to his professional and financial ties to Cassava as a consultant and member of its Scientific Advisory Board;
- Cassava and Barbier failed to disclose that Cassava's audit of Dr. Wang's laboratory in 2022 found it was "unacceptable and temporarily not qualified to provide biomarker analysis and research for services for any future Cassava studies;"

- Cassava and Burns failed to disclose her removal of a large portion of patients (roughly 40%) in reported cognition data, the average change in errors from baseline to day 28 for the full episodic memory data set (which showed no similar directional improvement for either the 50 mg or 100mg group compared with placebo), and that Burns was unblinded when she decided which patients to exclude from the reported results; and
- Cassava and Burns failed to disclose that the spatial working memory measurement reported in the Phase 2b results as showing cognitive improvement of up to 46% was a measurement selected by Burns only after she was unblinded and other spatial working memory results, including measurements identified as “key” prior to unblinding did not show directional improvement in patients receiving simufilam compared with placebo.

155. Without admitting or denying the allegations, Cassava, Barbier, and Burns consented to civil injunctions against future violations and agreed to pay civil penalties in the amount of \$40 million, \$175,000, and \$85,000, respectively. Barbier and Burns also agreed to officer-and-director bars of three and five years, respectively.

156. In a related order, the SEC charged Dr. Wang with manipulating the reported clinical results, with knowledge that Cassava would disclose the manipulated data when announcing the results of its Phase 2b Study (which ultimately occurred). Dr. Wang consented to cease and desist from future violations and pay a \$50,000 penalty.

157. Upon this news, Cassava’s stock decreased from a closing price of \$31.87 on September 26, 2024, to \$28.49 on September 27, 2024, a roughly 10.61% decline.

The Phase 2 Study Results

A. Defendants Made Materially False and Misleading Statements About the Phase 2 Study Results

158. Before the truth about the tainted Phase 2b Study and investigations related thereto was revealed, the Company also released the topline results for the Phase 2 Study and began to emphasize the Phase 2 Study results as supportive of simufilam’s potential.

159. On February 7, 2024, the Company announced the topline results for the Phase 2 Study in a press release titled “No Decline in Cognition Scores in Patients with Mild Alzheimer’s Disease Who Received Simufilam Continuously For 24 Months,” which quoted Barbier and listed Schoen as the person to contact for more information. On the same day, the Company filed an identical copy of the press release as an exhibit to a Form 8-K filed with the SEC, which Schoen signed.

160. The February 7, 2024 press release reported:

- Patients with mild Alzheimer’s disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer’s who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.65 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer’s, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.
- Patients with moderate Alzheimer’s who received simufilam treatment continuously for two years (n=32) declined 11.05 points on ADAS-Cog (± 1.91 SE) as a group.

161. After the topline results for the Phase 2 Study were released, Cassava’s stock price rose about 7.35%, closing at \$25.40 per share on February 7, 2024 after closing at \$23.66 per share on February 6, 2024.

162. On February 28, 2024, the Company issued a press release titled “Cassava Sciences Reports Full-year 2023 Financial Results and Corporate Updates,” which quoted Barbier and listed Schoen as the person to contact for more information. On the same day, the Company filed an identical copy of the press release as an exhibit to a Form 8-K filed with the SEC, which Schoen signed. The press released stated:

In February 2024, we reported that patients with mild Alzheimer's disease who received simufilam treatment continuously for two years . . . had no decline in ADAS-Cog scores . . . as a group. Patients with mild Alzheimer's who received simufilam treatment non-continuously for two years . . . declined 1 point on the ADAS-Cog . . . as group.

163. On that same day, the Company filed its 2023 Annual Report—signed by, *inter alia*, Barbier, Schoen, and Barry—which summarized the Phase 2 Study results, stating:

Average changes in ADAS-Cog scores, baseline to month 24, indicate the following:

- Patients with mild Alzheimer's disease who received simufilam treatment continuously for two years (n=47) had no decline in ADAS-Cog scores (± 1.51 SE) as a group.
- Patients with mild Alzheimer's who received simufilam treatment non-continuously (n=40) declined 1 point on ADAS-Cog (± 1.51 SE) as a group. Non-continuous treatment consisted of one year on open-label drug, six months on placebo and six months back on open-label drug.
- In patients with mild Alzheimer's, the largest separation between the continuous and non-continuous treatment groups occurred at the end of the 6-month randomized, placebo-controlled withdrawal phase.

[. . .]

Patients with mild Alzheimer's disease (n=87) started the 24 months study with MMSE 21-26, with ten exceptions [*i.e.*, patients with MMSE > 26 due to prior participation in a study of simufilam (n=2) or evidence of Alzheimer's disease pathology (n=8)]. Patients with moderate Alzheimer's disease started the 24 months study with MMSE 16-20, with one patient who entered with MSME 15.

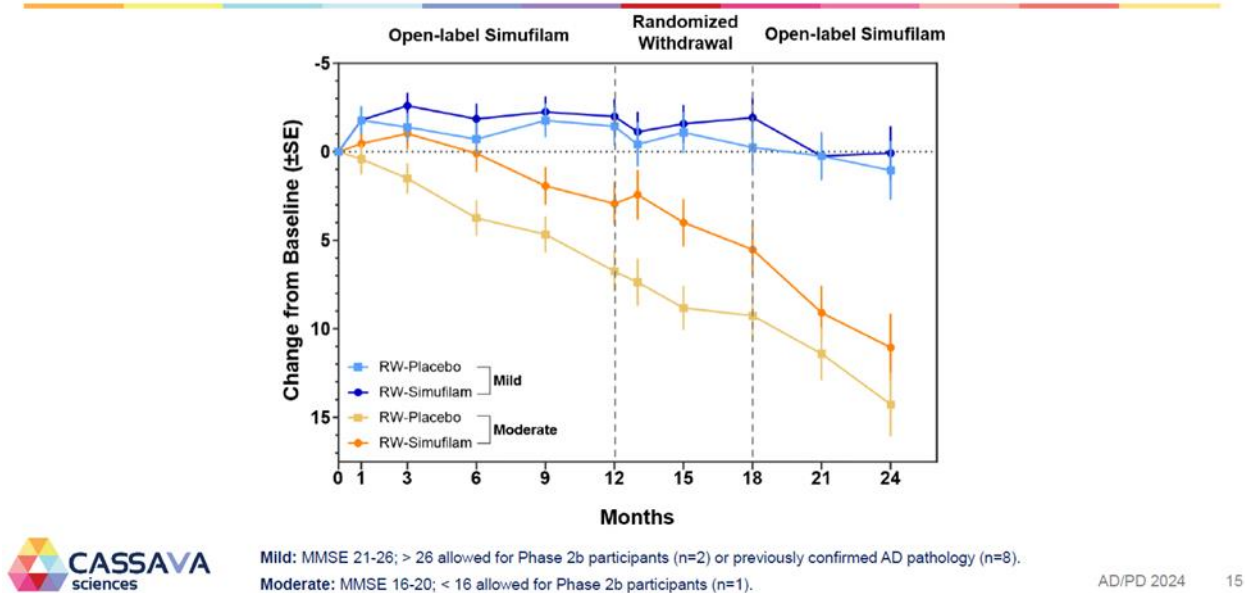
The pre-specified cognition endpoints were analyzed on the Full Analysis Set (FAS) by an independent consulting firm that specializes in complex statistical analysis of clinical trial results. The FAS population consists of all study participants who received at least one dose of treatment and have both baseline and at lease one post-baseline assessment. (Because FAS data is specific to each phase of a study, the FAS for the 24-month study may differ from the FAS for other phases).

164. Substantially similar summaries were included in the Company's Q1 2024 10-Q filed on May 10, 2024, which Barbier and Schoen signed; Q2 2024 10-Q, filed on August 8, 2024, which Barry and Schoen signed; and Q3 2024 10-Q, filed on November 7, 2024, which Barry and Schoen signed.

165. These statements (§§160, 162-164) were false or misleading because, as described more fully in §§102-114, they failed to disclose that (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the FAS population analyzed for the Phase 2 Study—contrary to what the Company reported and in violation of ICH E9 principles—consisted of those patients who completed a cognition assessment at baseline *and month 24*, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; (c) patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends, and thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer’s disease population was inconclusive and the results were not as “remarkable” as Defendants led investors to believe; and (d) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

166. The Company’s 2023 Annual Report, Q1 2024 10-Q filed on May 10, 2024, Q2 2024 10-Q filed on August 8, 2024, and Q3 2024 10-Q filed on November 7, 2024, and Burns’ presentation at the International Conference on Alzheimer’s and Parkinson’s Disease (AD/PD 2024) in Lisbon, Portugal in March 2024, also included the following chart summarizing the results of the Phase 2 Study:

Change in ADAS-Cog11 in Mild vs. Moderate



167. The chart was misleading because, as described more fully in ¶¶102-114, it reflected (a) only roughly 53% of the ITT population of the Phase 2 Study, (b) the results may have been biased because the population analyzed for the Phase 2 Study, in violation of ICH E9 principles, consisted of those patients who completed a cognition assessment at baseline *and month 24*, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed, and (c) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

168. On July 21, 2024, after the truth about the tainted Phase 2b Study and investigations related thereto had begun to emerge, the Company published “An Open Letter from Executive Chairman Rick Barry to the Cassava Community: Shareholders, Employees, Principal Investigators, Patients and their Loved Ones.” The Company attached an identical copy of the July

21, 2024 open letter as an exhibit to a Form 8-K filed with the SEC on July 22, 2024, which Schoen signed. The July 21, 2024 open letter quoted Barry emphasizing the Phase 2 Study results, stating: “I encourage you to study the cognition results from Cassava’s 24-month open-label Phase 2 clinical safety trial. *Those results were unlike any Alzheimer’s trial ever, reporting stable cognition for two full years in Alzheimer’s disease patients with mild dementia*” (emphasis added).

169. After the July 21, 2024 open letter was issued, Cassava’s stock price rose a staggering 27.28%, closing at \$12.83 per share on July 22, 2024 after closing at \$10.08 per share on the prior trading day, July 19, 2024.

170. Nonetheless, this statement (§168) was false or misleading because, as described more fully in §§102-114, it touted the Phase 2 Study results while failing to disclose that (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the population analyzed for the Phase 2 Study, in violation of ICH E9 principles, consisted of those patients who completed a cognition assessment at baseline *and month 24*, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; (c) patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends, and thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer’s disease population was inconclusive and the results were not as “remarkable” as Defendants led investors to believe; and (d) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

171. During the Company's Q2 2024 earnings call on August 8, 2024, Kupiec expressed confidence in simufilam's Phase 3 progress based on the results of the Phase 2 Study, stating:

I was excited when I joined Cassava, but I'm even more excited and optimistic now about simufilam and its chance for success in Phase 3. Simufilam continues to be safe and well tolerated in a very large number of patients. Plus, the data from the 24-month open-label Phase 2 safety study was remarkable in that patients with mild dementia apparently had no significant decline during that two-year treatment period. If this is true and replicated in Phase 3, it would represent an exceptional achievement and a significant advance in the field.

(Emphasis added).

172. This statement was false or misleading because Kupiec's excitement and optimism about simufilam was dependent on the "remarkable" Phase 2 Study results, but, as described more fully in ¶¶102-114: (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the population analyzed for the Phase 2 Study, in violation of ICH E9 principles, consisted of those patients who completed a cognition assessment at baseline **and month 24**, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; (c) patients with mild Alzheimer's disease performed similarly whether they were on simufilam or placebo, with no consistent trends, and thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer's disease population was inconclusive and the results were not as "remarkable" as Defendants led investors to believe; and (d) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

173. At the H.C. Wainwright's 26th Annual Global Investment Conference, held on September 9-11, 2024 in New York, New York with host, managing director of Biotechnology

Equity Research at H.C. Wainwright, Vernon T. Bernardino, Barry similarly emphasized simufilam's potential based on the Phase 2 results, stating during the Conference:

- ***“So this, . . . what we’ve seen so far, phase 2 results is, this to me was, you know, very impressive and one of the reasons I’m here, is that in the phase 2, you know, we started with 216 patients and it was, you know, there were certainly weaknesses in the trial: it was open label, everybody knew they were getting the drug, but after 12 months there were 216 patients. After 12 months, patients were given the option of remaining on the drug or terminating the trial, or if they wanted to remain on the drug the way to do it was 50% of those would be assigned to a placebo group for 6 months and 50% would stay on the drug. And then after that additional 6 months, everybody would be back on the drug. And what was persuasive about that trial, at least to me, was that the uh – at the end of 2 years the mild patients in the trial showed virtually no cognition decline. I mean that is unheard of. And, you know, again, there are weaknesses: phase 2 trial, open label, but uh – nobody has seen results like that before.”***
- ***“We’re really excited to see the data. It’s uh, you know, again, we look the - at what we saw in phase 2, we look at what we’ve seen in biomarkers, we look at the method of action. If this works this will be – you know this could be a disease modifying drug that treats Alzheimer’s and it may have – so far what we’ve seen – is a safety profile that’s just really pristine.”***
- ***“[I]n that phase 2, when the patients when into that period where, you know, half of them stayed on the drug and half went off. I actually found that really persuasive again, its – we’re going to see in phase 3 whether that holds up. The interesting thing is the patients that went on placebo for six months, they did decline, but they didn’t decline very much. To me, again I’m not a scientist, so take this with a grain of salt, that would suggest to me that the drug might actually have disease modifying qualities, because the patients should have declined a lot faster. We’ll see.”***

(Emphasis added).

174. The statements in ¶173 were false or misleading because Barry touted the Phase 2 Study results, but, as described more fully in ¶¶102-114, (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the population analyzed for the Phase 2 Study, in violation of ICH E9 principles, consisted of those patients who completed a cognition assessment at baseline *and*

month 24, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; (c) patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends, and thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer’s disease population was inconclusive and the results were not as “remarkable” as Defendants led investors to believe; and (d) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

175. Barry also reiterated the purportedly promising Phase 2 Study results, while downplaying the significance of the controversy surrounding the Phase 2b Study, in an open letter published on October 8, 2024—after the full truth about the tainted Phase 2b Study and investigations related thereto had emerged. The October 8, 2024 open letter, titled “An Open Letter from President and CEO Rick Barry to the Cassava Community: Patients and their Loved Ones, Caregivers, Principal Investigators, Shareholders and Employees” and attached to a Form 8-K filed with the SEC on the same day, which Schoen signed, stated in relevant part:

We have been asked a lot of questions about the SEC settlement and our Phase 2b study. The Phase 2b study was a 28-day trial with 64 patients across three arms that was not powered for statistical significance. *Given the inherent limitations of such small sample sizes, often referred to as the tyranny of small numbers, the Company believes that it is more helpful to focus on examining the two-year Phase 2 safety study that concluded earlier this year.*

The Phase 2 study enrolled 216 patients and consisted of a 12-month open-label treatment phase followed by a six-month “cognition maintenance study” at month 12 in which patients were randomized 1:1 between drug and placebo. For the last six months of the trial, all patients were again administered simufilam. Statistical analysis for the Phase 2 trial was performed by Pentara based on raw data collected at 16 clinical sites in the US.

Among the results of this Phase 2 study, 47 mild patients who took open-label simufilam continuously for 24 months experienced no mean decline in cognition as measured by ADAS-Cog11 as a group. Another 40 mild patients who took placebo

for six of the 24 months declined by a mean of one point as a group. *During the six-month randomization period, mild patients who were administered drug showed a trend of performing better as a group than those administered placebo*, though this small, randomized portion of the study was not powered for, and did not reach, statistical significance. Patients in the study with moderate Alzheimer's, including the 32 moderate patients who received simufilam treatment continuously for two years, declined in cognition much more than mild patients.

I recommend that you review the results for yourself.

[...]

We recognize the serious questions raised about some of the work performed at City University of New York, but those accusations do not negate the entire scientific body of evidence for our drug. We have previously highlighted independent research that supports the biological activity of simufilam, such as that conducted by researchers at the Cochin Institute in Paris and at Yale University. We are evaluating ways to make this information more readily accessible for journalists, investors, or anyone curious about our drug. We believe that some of our critics have mischaracterized the scientific and clinical basis supporting simufilam, while cherry-picking and taking out of context statements that we have made. We encourage interested parties to make their own determination in light of the information that we have provided.

[...]

If our Phase 3 program produces success, we will have made a significant contribution to the millions of patients and their families who live with the reality of this disease. If we fail, no one will be more crestfallen than we will be, but we also will know that we have done our best. Our patients deserve no less.

(Emphasis added).

176. After the October 8, 2024 open letter was issued, Cassava's stock price rose about 2.52%, closing at \$26.05 per share on October 8, 2024 after closing at \$25.41 per share on October 7, 2024.

177. Nonetheless, the statements in ¶175 were false or misleading because Barry touted the Phase 2 Study results but, as described more fully in ¶¶102-114, (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the population analyzed for the Phase 2 Study, in violation of ICH E9

principles, consisted of those patients who completed a cognition assessment at baseline *and month 24*, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; (c) patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends, and thus, the overall takeaway from the Phase 2 Study results in the mild Alzheimer’s disease population was inconclusive and the results were not as “remarkable” as Defendants led investors to believe; and (d) the Company did not disclose that the non-compliant FAS method was a poor predictor of Phase 3 results because the Phase 3 trials were based on the more rigorous ITT method.

B. The Previously Undisclosed Risk Materialized When the Phase 3 Trials Failed

178. On November 25, 2024, the previously undisclosed risk that the Phase 2 Study results were not the “remarkable” results supportive of simufilam’s progress that Defendants led investors to believe (for the reasons described in ¶¶102-114) began to materialize when Cassava announced in a press release titled “Cassava Sciences Topline Phase 3 Data Did Not Meet Co-Primary Endpoints,” which quoted Barry and Schoen, that the first Phase 3 trial, RETHINK-ALZ, had failed and the Company would be discontinuing the second Phase 3 trial, REFOCUS-ALZ. The Company also filed a Form 8-K on that same day attaching an identical copy of the press release, which Schoen signed.

179. The November 25, 2024 press release summarized that “[s]imufilam did not show a significant reduction in cognitive or function decline versus placebo in patients with mild-to-moderate Alzheimer’s disease in the ReThink-ALZ Phase 3 study.”

180. It also explained:

[T]he topline results from the Phase 3 ReThink-ALZ study of simufilam in mild-to-moderate AD did not meet each of the pre-specified co-primary, secondary and exploratory biomarker endpoints. The co-primary

endpoints were the change in cognition and function from baseline to the end of the double-blind treatment period at week 52, assessed by the ADAS-COG12 and ADCS-ADL scales, comparing simufilam to placebo. Simufilam continued to demonstrate an overall favorable safety profile.

(Emphasis added).

181. In the November 25, 2024 Press Release, Barry was quoted as saying:

The results are disappointing for patients and their families who are living with this disease and physicians who have been looking for novel treatment options. We took careful measures to enroll patients with mild-to-moderate AD. Despite that, the loss of cognition in the placebo group was less pronounced than was previously reported in other placebo-controlled studies in AD. We are working to understand this better . . . ***A result like this has implications in our second Phase 3 trial, ReFocus-ALZ. We have made the difficult decision to discontinue ReFocus-ALZ, given the nature of today's reported results.*** The complete 52-week dataset will be available from the study along with a large portion of 76-week data. We intend to report detailed analyses of both studies in the future. ***We will also be discontinuing the Open Label Extension study.***

(Emphasis added).

182. On that same day, Defendants hosted a business update call regarding the Phase 3 study topline results. During the call, Barry stated:

As outlined in our press release, the study failed to meet each of its prespecified co-primary endpoints as well as its secondary endpoints and exploratory plasma biomarker endpoints.

[. . .]

We took careful measures to enroll patients with mild to moderate Alzheimer's. Despite that, the loss of cognition in the placebo group was less pronounced than was previously reported in other placebo-controlled studies in AD. We're working to understand this better. The results are disappointing for patients and their families who are living with this disease and physicians who have been looking for novel treatment options.

A result like this has implications on our second Phase 3 trial, ReFocus. We have made the difficult decision to discontinue ReFocus-ALZ given the nature of today's results. Complete 52-week dataset will be available from this study, along with a large portion of the 76-week data. We intend to report detailed analyses of both studies in the future. We will also be discontinuing the Open Label Extension study.

183. Upon this news, Cassava's stock fell from a closing price of \$26.48 per share on November 22, 2024 to close at \$4.30 per share on November 25, 2024, a decline of about 83.76%.

184. Analysts reacted negatively. On November 26, 2024, H.C. Wainwright downgraded Cassava's rating to "Neutral," and in discussing simufilam's failure to meet endpoints in the Phase 3 ReThink-ALZ trial, stated: "We are surprised by the results *as Phase 2 studies suggested mechanism of action (MOA)-based and biomarker-based results supported high potential for a positive result with simufilam treatment vs. placebo*" (emphasis added).

185. Similarly, on November 25, 2024, Jones Research issued a "Hold" rating, emphasizing that "[s]imufilam failed to show a significant reduction in cognitive or functional decline versus placebo in mild-to-moderate Alzheimer's disease patients," "[t]he trial failed to meet the pre-specified co-primary, secondary and exploratory biomarker endpoints," and "Cassava discontinued the Phase 3 ReFocus-ALZ and open-label extension (OLE) study."

186. The previously undisclosed risk that the Phase 2 Study results were not the "remarkable" results supportive of simufilam's progress that Defendants led investors to believe (for the reasons described in ¶¶102-114) continued to materialize on March 25, 2025, when the Company reported the topline results from the second Phase 3 study, REFOCUS-ALZ, in a press release titled "Cassava Sciences Reports Topline Phase 3 REFOCUS-ALZ Data," in which Barry and Schoen were quoted. On the same day, the Company filed a Form 8-K with the SEC that attached an identical copy of the March 25, 2025 press release, which Schoen signed.

187. The March 25, 2025 press release summarized that "[s]imufilam did not show a significant reduction in co-primary endpoints of cognitive or functional decline versus placebo in patients with mild-to-moderate Alzheimer's disease," and that "Cassava's Alzheimer's disease development program with simufilam will be completely discontinued by the end of Q2 2024."

188. It also explained as follows:

Topline data indicate that REFOCUS-ALZ did not meet each of the prespecified co-primary, secondary, and exploratory biomarker endpoints. The co-primary endpoints were the change in cognition and function from baseline to the end of the double-blind treatment period at week 76, assessed by the ADAS-COG-12 and ADCS-ADL scales, comparing simufilam to placebo. REFOCUS-ALZ enrolled 1,125 patients and was discontinued on November 25, 2024, following the report that a prior 52-week Phase 3 study, RETHINK-ALZ, did not meet its co-primary endpoints. A large portion of subjects enrolled in REFOCUS-ALZ completed their final study visit prior to the termination of the trial. Simufilam continued to demonstrate an overall favorable safety profile.

189. In the March 2025 Press Release, Barry was quoted as saying:

We are disappointed that the results of REFOCUS-ALZ and RETHINK-ALZ showed no treatment benefit for patients with mild-to-moderate Alzheimer’s disease. These results were unambiguous. . . . We are deeply grateful for the dedication and committed efforts of study investigators and site teams, who enabled us to conduct these trials with integrity and scientific rigor and whose efforts provided a clear data read out Cassava will discontinue all efforts to develop simufilam for Alzheimer’s disease and we expect to phase out the program by the end of Q2 2025.”

190. Barry also reported “[w]e remain dedicated to our mission of developing novel medicines for central nervous system disorders” and that the Company had “initiated preclinical studies to evaluate simufilam’s potential as a treatment for TSC-related epilepsy.”

191. Upon this news, Cassava’s stock fell from a closing price of \$2.80 per share on March 24, 2025 to close at \$1.90 per share on March 25, 2025, a 32.14% drop.

ADDITIONAL SCIENTER ALLEGATIONS

The Individual Defendants Were Privy to Evidence Substantiating the Allegations of Research Misconduct

192. Defendants knew that their misstatements regarding the tainted Phase 2b Study and the investigations related thereto were false or misleading when made because, as set forth below, they were aware, or should have been aware, of both public and non-public information regarding

the extensive ongoing and past investigations, as well as the evidence of research misconduct that had already been uncovered related to the Phase 2b Study.

193. The Individual Defendants managed the day-to-day affairs of the Company during the Class Period.

194. During the Class Period, Barbier was the President and CEO of the Company and Chairman of the Board until he resigned on July 15, 2024. Barbier regularly spoke on the Company's behalf in press releases, conference calls, and in SEC filings. Indeed, the Company's 2023 Annual Report emphasized "We are highly dependent on our management, particularly our President and Chief Executive Officer, Remi Barbier" (emphasis added).

195. During the Class Period, Kupiec was the Chief Medical Officer of the Company and prior to the Class Period, between January 4, 2021 and December 20, 2022, Kupiec was the Chief Clinical Development Officer and served as a member of the executive management team. In that role, according to his employment agreement, Kupiec had "broad responsibility for the strategy, design, conduct *and monitoring* of clinical research plans and programs," including, "*active participation in on-going* and future *clinical studies*; oversee[ing], identify[ing], monitor[ing] and resolv[ing] operational aspects of clinical studies, provid[ing] scientific and clinical leadership; *interpret[ing] study data*; assist[ing] with regulatory documents; and perform[ing] other duties as needed" (emphasis added). As Chief Clinical Development Officer, Kupiec was tasked with leading the Phase 3 clinical development strategy for simufilam. He also was familiar with the discussions during the End-of-Phase 2 meeting with the FDA, which he commented on in the Company's February 22, 2021 press release announcing the completion of the meeting.

196. Schoen has served as CFO of the Company since 2018. As CFO during the Class Period, he was responsible for assessing the potential financial impact for the Company of the ongoing investigations into research misconduct, as well as any related settlements.

197. Burns was the Senior Vice President of Neuroscience during the Class Period until July 16, 2024, and reported to Kupiec. Before the Class Period, Burns played a critical role in the development of simufilam, including, *inter alia*, as a co-inventor and collaborator with Dr. Wang on multiple scientific journal articles and grant applications. She was also involved in the controversial Phase 2b Study. On May 14, 2020, Burns sent Dr. Wang a document that enabled him to unblind himself as to some patients in the Phase 2b Study before he performed the analysis of CSF samples. Burns also received the results of cognition testing during the Phase 2b Study, which showed no meaningful improvement in patient cognition, and while unblinded, she removed 40% of the patient population from the final results. At all relevant times, Burns and Barbier were married and presumably shared information with each other.

198. Barry has been a director on the Board of Directors since 2021. On July 17, 2024, he was appointed Executive Chairman of the Board and the Company's principal executive officer while the Company undertook a search for a new permanent CEO. Then, on September 9, 2024, Barry was named the permanent CEO of the Company, and another individual assumed the role of Chairman of the Board. Before being appointed principal executive officer, Barry was a member of the Board that engaged Orrick to conduct an internal investigation into the allegations contained in the Citizen Petition and that empowered an *Ad Hoc* Investigation Committee to investigate both the information provided by the SEC during ongoing discussions about its investigation, as well as the information contained in Dr. Wang's indictment.

199. In these roles, the Individual Defendants were privy to confidential information concerning the controversy surrounding the Phase 2b Study.

200. Barbier, Schoen, and the Company knew or should have known that the October 12, 2023 response to the CUNY Report (§123), which denied the findings in the CUNY Report that Burns bore some responsibility for the alleged misconduct, was false or misleading when made because Barbier and Shoen caused the Company to issue the response and any reasonable investigation into Burns' involvement in the research misconduct to ensure the response's accuracy would have uncovered her involvement. The Company had in its possession Burns' May 14, 2020 email to Dr. Wang attaching a document that enabled him to unblind himself as to a number of patients in the Phase 2b Study before he conducted the final analysis. Burns—who presumably spoke about the controversy with her husband, Barbier—certainly knew about her own involvement in the research misconduct, including, *inter alia*, enabling Dr. Wang to unblind himself and removing a large portion of patients in reported cognition data (which showed no improvement in patient cognition) after she was unblinded.

201. Defendants were also well aware of the accusations of research misconduct and data manipulation related to the Phase 2b Study because it was widely publicized beginning in August 2021, including with the filing of the Citizen Petition, news articles reporting on the controversy and resulting investigations, the publicly available September 2022 FDA inspection report identifying deficiencies related to the Phase 2b Study after an audit of Dr. Wang's laboratory, the CUNY Report leaked in October 2023 that found “evidence highly suggestive of deliberate scientific misconduct by Dr. Wang” (including, *inter alia*, “image aberrations that may be consistent with the fabrication/manipulation of the data”), and the various lawsuits filed against the Company and its executives beginning in 2021.

202. The Individual Defendants also knew, or should have known absent severe recklessness, that there was some legitimacy to the accusations of research misconduct because, based on their roles at the Company and involvement in causing the Company to issue the false or misleading statements, as discussed more fully below, they were privy to the Company's 2022 audit of Dr. Wang's laboratory related to his work on the Phase 2b Study, the evidence of Burns' involvement in the research misconduct in the Company's possession, and Orrick's internal investigation of the allegations in the Citizen Petition.

203. Between April and September 2022, Cassava's Senior Director of Clinical Quality Systems audited Dr. Wang and his laboratory, reviewing documents related to the Phase 2b Study and conducting a site visit to Dr. Wang's laboratory at CUNY. The audit found critical issues with the laboratory and Dr. Wang's practices, including "lack of experiment logbooks/notebooks for all study/research for work being performed," and determined that Dr. Wang's laboratory at CUNY was "unacceptable and temporarily not qualified to provide biomarker analysis and research services for any future Cassava studies."

204. Barbier and Burns (who was Dr. Wang's primary point of contact) were both generally aware of the findings in the report. Kupiec likewise knew or should have known about the 2022 audit findings because he was responsible for overseeing clinical studies at that time. Schoen also knew or should have known about the 2022 audit findings given that he caused the Company to issue a response the CUNY Report on October 12, 2023 denying the allegations of research misconduct and any reasonable investigation to ensure the response's accuracy would have uncovered the Company's own earlier audit, which similarly found critical issues with Dr. Wang's laboratory and practices.

205. Further, by February 8, 2024, Orrick had completed an internal investigation of the allegations raised in the Citizen Petition, pursuant to which they were provided access to “Company personnel, communications, documents, data, and information” and counsel “was assisted by technical experts with relevant experience and knowledge.” Any reasonable investigation—especially an investigation on the heels of widely publicized accusations that the Company, Dr. Wang, and even Burns had engaged in research misconduct during the Phase 2b Study—would have uncovered, at a minimum, the Company’s 2022 audit findings and the evidence in the Company’s possession of Burns’ involvement (*i.e.*, Burns’ May 14, 2020 email to Dr. Wang attaching a document that enabled him to partially unblind himself as to some Phase 2b Study participants before conducting the final analysis). The compelling inference to be drawn if Orrick did not uncover such evidence is that Orrick was actively misled during the investigation.

206. Moreover, given the abundance of information in the public sphere regarding the alleged research misconduct related to the Phase 2b Study, the compelling inference to be drawn is that if any of the Individual Defendants did not know about the evidence substantiating the allegations that was already in the Company’s possession, they did not know because they were willfully blind.

207. Thus, Defendants either knew or should have known that the statements about the tainted Phase 2b Study and the investigations related thereto (§§125, 127, 129-130, 132, 134-135) were false or misleading when made.

208. Barry and Schoen likewise knew, or should have known, that the statements made in the July 17, 2024 press release about Barbier’s and Burn’s departure from the Company, and the Company’s commitment to transparency and accountability (§§145, 147), were false or

misleading when they were made because by that time, they knew the reason for Barbier's and Burn's departure from the Company.

209. Schoen either knew or should have known about Burns' involvement in the research misconduct by October 2023 because of his involvement in issuing the Company's response to the CUNY Report, which had alleged that Burns bore some responsibility for the research misconduct. At latest, Schoen and Barry knew or should have known about Barbier's and Burns' involvement in the research misconduct by July 1, 2024 because the Company's July 1, 2024 Form 8-K, which Schoen signed, revealed that the SEC was investigating them (without disclosing their identities) and that the *Ad Hoc* Investigation Committee, empowered by Barry and the other members of the Board, had discovered the email Burns sent to Dr. Wang that enabled Dr. Wang to unblind himself as to some patients in the Phase 2b Study before he performed the analysis of CSF samples.

210. Indeed, Barry later discussed his awareness of the *Ad Hoc* Investigation Committee's internal investigation in his October 8, 2024 open letter, describing it as "painstakingly thorough" and stating it "enabled us to disclose supplemental information relating to the committee's findings on July 1, 2024."

211. Accordingly, Barry and Schoen knew that the July 17, 2024 press release's discussion of Burns' and Barbier's departure from the Company (§§145, 147) was false or misleading when made.

Defendants' Access to and Review of the Phase 2 Study Results Supports Their Scienter

212. Defendants also knew that their statements regarding the Phase 2 Results were false or misleading when made based on their access to and review of the Phase 2 Study data.

213. While part of the Phase 2 Study was ongoing, Kupiec was still Chief Clinical Development Officer and was responsible for overseeing and monitoring the study and interpreting the study data.

214. By the time the Phase 2 Study was completed, Kupiec had assumed the role of Chief Medical Officer. However, as Kupiec admitted during the Q2 2024 Earnings Call on August 8, 2024, he also monitored patient data from the clinical trials as part of his role as Chief Medical Officer: “As Chief Medical Officer for Cassava, I’m ultimately responsible for the safety of [study] patients, and I spend a lot of time reviewing all types of safety, lab, and [electrocardiogram] reports along with the medical monitor”

215. Thus, Kupiec had access to the data and information regarding the Phase 2 Study, including the Phase 2 Study results, and he reviewed and interpreted the data. Accordingly, Kupiec either knew or should have known that the Company’s representations regarding the Phase 2 Study results were false or misleading.

216. Based on their positions with the Company, Barbier, Barry and Schoen, likewise, had access to data underlying the Phase 2 Study Results.

217. Given that Barbier, Barry, and Schoen signed and/or were quoted in the public documents that painted a misleading picture about the Phase 2 Study results—*i.e.*, the Form 8-Ks attaching February 7, 2024 and February 28, 2024 press releases signed by Schoen; the 2023 Annual Report signed by Barbier, Schoen and Barry; the Q1 2024 10-Q signed by Barbier and Schoen; the Q2 2024 10-Q signed by Barry and Schoen; and the Q3 2024 10-Q signed by Barry and Schoen—they had an obligation to ensure that the Company’s disclosures about the Phase 2 Study results in those filings were truthful and accurate.

218. A reasonable review of the underlying data for the Phase 2 Study results would have revealed that the Phase 2 Study results were not as favorable as presented in those filings because: (a) only roughly 53% of the ITT population of the Phase 2 Study was analyzed in the Phase 2 Study results; (b) the results may have been biased because the FAS population consisted of those patients who completed a cognition assessment at baseline *and month 24*, and thus, patients who were not available for a cognition assessment at the conclusion of the trial or who had dropped out of the trial before completion were excluded from the patient population analyzed; and (c) patients with mild Alzheimer’s disease performed similarly whether they were on simufilam or placebo, with no consistent trends.

219. Barry also repeatedly spoke about the Phase 2 Study results publicly, including at conferences, in press releases, and on the Company’s earnings call, which supports the inference that Barry either knew or should have known about the problematic aspects of the Phase 2 Study results, and that the Phase 2 Study results were not as “remarkable” as Defendants led investors to believe.

Defendants Were Motivated to Mislead Investors About the Tainted Phase 2b Study, the Related Investigations, and the Phase 2 Study Results

220. Defendants were motivated to mislead investors in order to raise capital critical for the continued development of simufilam.

221. On December 12, 2023, in a press release titled “Cassava Sciences Announces Dividend Distribution of Warrants to Shareholders,” the Company announced that on or about January 3, 2024, it would be distributing warrants—four warrants for every ten shares of common stock—to shareholders of record as of December 22, 2023.

222. Barbier explained in the December 12, 2023 press release: “We intend to use the cash proceeds from the exercise of the warrants to support our ongoing Phase 3 clinical development of oral simufilam in people with Alzheimer’s disease.”

223. The Company’s 2023 Annual Report also acknowledged that the Company may need additional cash as the Company “continue[s] [the] Phase 3 program with simufilam.”

224. As explained further below, simufilam was the Company’s *only* therapeutic drug candidate during the Class Period and the Company’s future financial success and continued vitality was entirely dependent on simufilam ultimately generating revenue through sales. Thus, ensuring that the Company had adequate capital to continue developing simufilam was critical.

225. Accordingly, Defendants were highly motivated to mislead investors about the controversy surrounding the Phase 2b Study and the Phase 2 Study results in order to induce investors to exercise the warrants so that the Company could raise money to continue to develop simufilam.

226. Defendants were successful. On January 3, 2024, the Company completed the distribution of warrants and between January 3, 2024 and February 26, 2024, a total of approximately 659,000 warrants were exercised, resulting in the Company receiving gross proceeds of approximately \$21.8 million.

227. Indeed, a March 5, 2024 analyst report from H.C. Wainwright & Co. stated: “Initial warrant exercise underscores strong support for the company.”

The Misstatements Related to the Company’s Core Operation, Further Bolstering the Inference of Scienter

228. Defendants’ roles at the Company, described in ¶¶194-198, along with the other special circumstances discussed below, further bolster the inference of scienter.

229. Both before and during the Class Period, Cassava was a small company, with only 24 full-time employees as of December 31, 2021, 26 full-time employees as of December 31, 2022, 29 full-time employees as of December 31, 2023, and 30 full-time employees as of December 31, 2024.

230. Simufilam was Cassava’s *only* therapeutic drug candidate during the Class Period. The Company had no source of revenue and incurred net losses in each reporting period since inception. The Company invested significant financial resources in the research and development of simufilam, and its future financial success and continued vitality was entirely dependent on simufilam ultimately generating revenue through sales.

231. Indeed, the Company’s 2023 Annual Report disclosed the risk that Cassava was “heavily dependent on the success of simufilam” and “[i]f this product candidate fails one or both of our ongoing Phase 3 trials, or does not receive regulatory approval, ***we will be unable to generate product revenue*** and our business will be harmed” (emphasis added).

232. Each of the Individual Defendants was focused on the successful development of simufilam for eventual commercial sale and was motivated to mislead investors about the research misconduct during the Phase 2b Study, the ongoing investigations, and the less favorable results from the Phase 2 Study in order to make simufilam’s prospects appear better and garner support for the drug’s continued development.

233. The misleading nature of the statements downplaying the investigations into the alleged research misconduct and touting the Phase 2b Study and Phase 2 Study results, was readily apparent to Defendants because, as discussed more fully above in ¶¶193-219, they were aware, or should have been aware, of the extensive ongoing and past investigations into research misconduct,

the evidence of research misconduct that had been uncovered, and the data underlying the Phase 2 Study results presented to investors.

234. Accordingly, because any developments related to simufilam, including these developments undercutting simufilam's potential, were critical to the Company's core operation, Defendants must have been aware of them.

LOSS CAUSATION

235. As a result of Defendants' materially false or misleading statements and omissions of material fact, Cassava stock traded at artificially inflated prices during the Class Period. Relying on the integrity of the market price for Cassava securities and public information related to Cassava, Plaintiffs and the other members of the Class purchased or otherwise acquired Cassava securities at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact alleged herein.

236. Absent Defendants' misrepresentations and omissions of material fact, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Cassava securities at the artificially inflated prices at which they traded.

237. Plaintiffs and the other members of the Class were damaged when the material facts misrepresented or concealed by Defendants were revealed through the disclosure of new information concerning Cassava on the dates listed below, each of which directly and proximately caused declines in the price of Cassava securities by removing the artificial inflation in the price of Cassava's securities that resulted from Defendants' fraud.

238. After the Company's Q3 2023 10-Q, filed on November 7, 2023, downplayed the government investigations that had been ongoing since 2021, the Company's stock rose about 4.3%, closing at \$22.30 per share on November 7, 2023 after closing at \$21.38 per share on November 6, 2023.

239. Cassava's stock price fell from a closing price of \$18.95 per share on June 27, 2024 to close at \$12.35 per share on June 28, 2024, a decline of about 34.83%, when on June 28, 2024, the truth about the investigations into research misconduct began to trickle out after a federal grand jury indicted Dr. Wang, Cassava's former consultant who conducted the final analysis for the Phase 2b Study, for allegedly engaging in a scheme to fabricate and falsify scientific data in grant applications made to the NIH on behalf of himself and Cassava.

240. Cassava's stock price fell further from a closing price of \$12.35 per share on June 28, 2024 to close at \$12.14 per share on July 1, 2024, when Cassava disclosed in a Form 8-K that the SEC and DOJ had been investigating the Company and two senior employees regarding the Phase 2b Study and the Company possessed the email from Burns to Dr. Wang that enabled him to unblind himself as to some patients in the Phase 2b Study before he performed the analysis of CSF samples.

241. Upon this news, on July 1, 2024, H.C. Wainwright & Co downgraded Cassava from "Buy" to "Neutral," reasoning "the matter that is inescapable is that Dr. Wang has been formally charged with false statements and fraud related to Phase 1 and Phase 2 study results used as evidence to support simufilam's advancement into late-stage clinical testing" and "we believe this controversy could be a significant long-term challenge to realizing upside in Cassava stock."

242. On the same day, Jones Research likewise downgraded Cassava from "Buy" to "Hold," stating: "Following the federal grand jury indictment of the former consultant of [Cassava], [Dr. Wang], last Friday, and today's 8-K mentioning the DOJ and SEC investigations into the Company and two senior employees of the Company, we see multiple sources of uncertainties to be able to meaningfully value the stock."

243. The truth continued to emerge on August 8, 2024, when the Company disclosed, for the first time, the breadth of the government investigations spanning roughly three years, and that the Company was in “advanced stages of discussions” with the SEC to resolve the SEC investigation. The Company also advised investors not to place “undue reliance” on the Phase 2b Study results. Upon this news, Cassava’s stock fell from a closing price of \$30.20 per share on August 7, 2024 to close at \$26.02 per share on August 8, 2024, a decline of about 13.84%.

244. The full truth about the extent of the research misconduct and who was involved emerged on September 26, 2024 after the close of trading when the SEC filed charges against Cassava, Barbier, and Burns related to their misleading statements about the results of the Phase 2b Study and announced that Cassava, Barbier, and Burns agreed to pay civil penalties in the amount of \$40 million, \$175,000, and \$85,000, respectively. Upon this news, Cassava’s stock decreased from a closing price of \$31.87 on September 26, 2024, to \$28.49 on September 27, 2024, a roughly 10.61% decline.

245. When the Company released the topline results for the Phase 2 Study on February 7, 2024, the Company’s stock price rose about 7.35%, closing at \$25.40 per share on February 7, 2024 after closing at \$23.66 per share on February 6, 2024.

246. Similarly, when Barry’s open letter touting the Phase 2 Study results and encouraging investors to focus on them was published on July 21, 2024, the Company’s stock price rose 27.28%, closing at \$12.83 per share on July 22, 2024 after closing at \$10.08 per share on the prior trading day, July 19, 2024.

247. The stock price, again, rose after Barry’s October 8, 2024 open letter—published after the full truth about the tainted Phase 2b Study and the investigations related thereto had emerged—advised investors that “it is more helpful to focus on” the Phase 2 Study than the Phase

2b Study. Cassava's stock price rose about 2.52%, closing at \$26.05 per share on October 8, 2024 after closing at \$25.41 per share on October 7, 2024.

248. However, the previously undisclosed risk that the Phase 2 Study results were not the "remarkable" results, supportive of simufilam's potential, that Defendants led investors to believe began to materialize on November 25, 2024 when Cassava reported that simufilam failed to meet the co-primary endpoints in the RETHINK-ALZ Phase 3 study and the Company would be discontinuing the REFOCUS-ALZ Phase 3 study, resulting in Cassava's stock falling from a closing price of \$26.48 per share on November 22, 2024 to close at \$4.30 per share on November 25, 2024, a staggering roughly 83.76% decline.

249. Upon this news, on November 26, 2024, H.C. Wainwright downgraded Cassava from "Buy" to "Neutral" and expressed surprise that simufilam had failed to meet endpoints in the Phase 3 trial, given the purportedly promising Phase 2 results: "We are surprised by the results as Phase 2 studies suggested mechanism of action (MOA)-based and biomarker-based results supported high potential for a positive result with simufilam treatment vs. placebo."

250. The previously undisclosed risk continued to materialize on March 25, 2025, when the Company reported that simufilam also failed to meet the endpoints in the REFOCUS-ALZ Phase 3 study and that Cassava would be discontinuing its Alzheimer's disease development program by the end of Q2 2024. Upon this news, Cassava's stock fell from a closing price of \$2.80 per share on March 24, 2025 to close at \$1.90 per share on March 25, 2025, a 32.14% drop.

PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

251. Plaintiffs and the members of the Class are entitled to a presumption of reliance under the fraud-on-the-market doctrine pursuant to *Basic Inc. v. Levinson*, 485 U.S. 224 (1998), and are entitled to a presumption of reliance for omissions of material fact for which there was a duty to disclose pursuant to *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972).

252. At all relevant times, the market for Cassava's securities was efficient for the following reasons:

- (a) Cassava's securities met the requirements for listing and were listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;
- (b) As a regulated issuer, Cassava filed periodic public reports with the SEC;
- (c) Cassava communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services, publications on its website, and through other wide-ranging public disclosures, such as conference calls and communications with the financial press, securities analysts, and other similar reporting services;
- (d) Cassava was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period, and which were publicly available and entered the public marketplace; and
- (e) Unexpected material news about Cassava was reflected in and incorporated into the Company's stock price during the Class Period.

253. As a result, the market for Cassava's securities reasonably and promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of Cassava's securities, causing Cassava's securities to be artificially inflated. All purchasers and acquirers of Cassava's securities during the Class Period suffered similar injury through their purchase or acquisition of Cassava's securities at artificially inflated prices, and a presumption of reliance applies.

254. Plaintiffs and the other Class members purchased Cassava securities, without knowledge of the misrepresented and/or omitted facts, between when Defendants misrepresented or failed to disclose material facts necessary to make the statements they made not misleading and when the true facts were disclosed or the risk materialized. Accordingly, Plaintiffs and the other members of the Class purchased Cassava's securities at artificially inflated prices and are entitled to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

NO SAFE HARBOR

255. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false or misleading herein, which relate to facts and conditions existing at the time the statements were made.

256. To the extent certain of the statements alleged to be false or misleading may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

257. Defendants are also liable for any false or misleading forward-looking statements because, at the time each forward-looking statement was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and the forward-looking statement was authorized or approved by an executive officer of Cassava who knew that the forward-looking statement was false or misleading when made.

CLASS ACTION ALLEGATIONS

258. Plaintiffs bring this action on their own behalf and as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a Class consisting of all persons or entities who purchased or otherwise acquired Cassava's securities during the period

between October 13, 2023 and March 25, 2025, inclusive, and were damaged thereby (the “Class”). Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

259. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cassava’s securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Cassava or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. Upon information and belief, the Company’s shares are held by thousands of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

260. Plaintiffs’ claims are typical of the claims of the members of the Class as all members of the Class were similarly affected by Defendants’ wrongful conduct complained of herein.

261. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class actions and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

262. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are the following:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts;

(c) whether the Individual Defendants caused Cassava to issue false and misleading statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(e) whether the prices of Cassava's securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

263. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
(Against All Defendants for Violations of Section 10(b) and Rule 10b-5 Promulgated Thereunder)

264. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

265. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

266. During the Class Period, Defendants made or caused Cassava to issue various untrue statements of material fact and/or omitted material facts from their public disclosures that were necessary to make the statements made, in light of the circumstances under which they were made, not misleading, including the statements specified above. This was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Cassava securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Cassava's securities at artificially inflated prices.

267. Defendants are individually and collectively responsible for making such statements by virtue of having made the public statements or otherwise prepared, approved, signed, and/or disseminated documents containing those statements to the investing public.

268. By virtue of their positions at the Company, and for the additional reasons discussed herein, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants.

269. As a result of the foregoing, the market price of Cassava securities was artificially inflated during the Class Period. Relying on the materially false and misleading statements described herein or upon the integrity of the market, Plaintiffs and other Class members purchased or otherwise acquired Cassava securities at prices that were artificially inflated by the fraud described herein.

270. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Cassava stock during the Class Period when the true facts were subsequently disclosed or the previously undisclosed risk concealed by the misstatements materialized, causing the market price of Cassava securities to decline.

271. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities or would not have purchased or otherwise acquired them at the inflated prices that were paid.

272. By reason of the conduct alleged herein, Defendants are liable to Plaintiffs and members of the Class for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT II

(Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act)

273. Plaintiffs repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

274. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew adverse non-public information about Cassava's misstatements.

275. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to promptly correct any public statements issued by Cassava which had become materially false or misleading. In this capacity, the Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged herein to be false

or misleading prior to and/or shortly after those statements were made, and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

276. Because of their positions of control and authority as senior officers and/or directors of Cassava, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the contents of the various statements, reports, press releases, and public filings alleged to give rise to the primary violations alleged herein.

277. The Individual Defendants, therefore, were “controlling persons” of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged, which artificially inflated the market price of Cassava’s securities.

278. By reason of such conduct, the Individual Defendants are liable to Plaintiffs and the other Class members for violations of Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;
- B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class as a result of Defendants’ wrongdoing alleged herein;
- C. Awarding Plaintiffs and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

Dated: August 25, 2025

Respectfully submitted,

/s/ Murielle J. Steven Walsh

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on August 25, 2025, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the email addresses on the attached Electronic Mail Notice List, and I hereby certify that I caused the mailing of the foregoing via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

/s/ Murielle J. Steven Walsh

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

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